

# Guidance on harmonised information relating to emergency health response – Annex VIII to CLP

Guidance to Regulation (EC) No 1272/2008 on classification, labelling  
and packaging (CLP) of substances and mixtures

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## 1 PREFACE

2 This document is the *Guidance on the harmonised information relating to emergency health*  
3 *response*. It is a comprehensive technical and scientific document on the implementation of  
4 Article 45 and Annex VIII to Regulation (EC) No 1272/2008 on the classification, labelling and  
5 packaging of substances and mixtures (CLP<sup>1</sup>). CLP is based on the Globally Harmonised  
6 System of Classification and Labelling of Chemicals (GHS) and is implementing the provisions  
7 of the GHS within the EU. CLP now has relevance for European Economic Area (EEA) countries  
8 (i.e. it is implemented in the EU countries and in Norway, Iceland and Liechtenstein)<sup>2</sup>.

9 The objective of this document is to provide detailed guidance on the obligation to submit to  
10 Member States responsible bodies relevant information on hazardous mixtures placed on the  
11 market for formulating preventative and curative measures in case of accidents. The guidance  
12 is developed to primarily assist companies placing hazardous mixtures on the market in  
13 complying with their obligations. It is also intended to be a support tool for the appointed  
14 bodies in the Member States.

15 This guidance document was developed by ECHA with the support of a dedicated Working  
16 Group consisting of experts from Industry, Member State appointed bodies and poison centres.  
17 The project started in April 2017 and the working group had meetings and continuous  
18 discussions to develop the guidance text until December 2017. Finally the text was  
19 consolidated and edited by ECHA and underwent the formal consultation with ECHA Partners  
20 during 2018.

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<sup>1</sup> Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006 [OJ L 353, 31.12.2008, p. 1].

<sup>2</sup> CLP was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 106/2012 of 15 June 2012 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement (OJ L 309, 8.11.2012, p. 6–6).

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## 1. Introduction

### 1.1 General introduction

A large number of products (e.g. detergents, paints, adhesives) containing chemical mixtures are placed on the EU market and used both by the general public in their everyday lives as well as by professionals in their working environments.

Chemical products are in general considered to be safe when their use instructions are followed. Nevertheless, unintentional exposure to chemicals can occur, for example due to inappropriate use or accidents. When this happens, immediate access to relevant information on the chemical product is crucial for medical staff and those who provide emergency responses.

### 1.2 Legal background

In 1988, Council Directive 88/379/EEC<sup>3</sup> required the Member States to appoint a body responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous. This information was to be used to meet any medical demand by formulating preventative and curative measures, in particular in emergencies. In 1999, the Directive was repealed by Directive 1999/45/EC<sup>4</sup>, which provided for a similar obligation.

Many Member States have therefore already had in place for a long time, a system for collecting information from companies that were placing dangerous mixtures on the market and have established bodies, called poison centres, to provide medical advice in health emergencies. The information collected has been used to meet medical demands of the poison centres. Depending on the Member State, physicians and other medical staff, workers and the general public were also able to contact the poison centres to receive advice on medical treatment in the event of a poisoning or accidental exposure incident.

The existing requirement for the EU Member States<sup>5</sup> to appoint a body for receiving information on the composition of hazardous mixtures to enable the formulation of preventative and curative measures, was incorporated in Article 45 of the CLP Regulation ((EC) No 1272/2008) which entered into force on 20 January 2009, repealing Directive 1999/45/EC.

The absence of harmonised information requirements led to considerable variation in the existing national notification systems, data formats and information requirements. Thus companies placing mixtures on the market in different Member States needed to submit similar information multiple times and in different formats. This diversity led to inconsistencies in the information available to medical personnel in cases of poisoning or accidental exposure incidents in different Member States.

The European Commission was assigned the obligation to carry out a review, as foreseen in Article 45 of the CLP Regulation, to assess the possibility of harmonising the information. The

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<sup>3</sup> Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

<sup>4</sup> Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

<sup>5</sup> Please note that whenever there is a reference to the Union (EU) in this document, the term also covers the EEA countries Iceland, Liechtenstein and Norway. See footnote 1.

1 review was carried out in consultation with stakeholders and with the support of the European  
2 Association of Poison Centres and Clinical Toxicologists (EAPCCT). Following the review,  
3 Commission Regulation (EU) 2017/542 was adopted. The new Annex VIII entered into force on  
4 12 April 2017. The provisions of the Annex will apply to mixtures for consumer use from 1  
5 January 2020, for use by professionals from 1 January 2021, and for mixtures for industrial  
6 use from 1 January 2024.

7 Annex VIII sets provisions to harmonise, in terms of format and content, the information  
8 relating to emergency health responses that companies placing hazardous mixtures, as  
9 specified in the Annex, on the EU market are required to submit to the bodies appointed by  
10 each Member State (i.e. the “appointed bodies”). The required information includes, among  
11 other things, the clear identification of the mixture and of the economic operator responsible  
12 for the placing on the market<sup>6</sup>, information on the composition and hazardous ingredient  
13 substances and on the intended use through a system of harmonised categories. The  
14 information must be submitted by electronic means in a specified format, which enables the  
15 appointed bodies to easily retrieve the relevant information. A unique formula identifier (“UFI”:  
16 addressed in detail in section 4) will allow the poison centres to unambiguously identify the  
17 composition of the mixture and propose the appropriate medical treatment in the event of  
18 poisoning.

19 The information required by Annex VIII is available for use by the poison centres, who have  
20 the task to provide medical advice to the general public and medical practitioners in the event  
21 of an emergency. The information can, according to Article 45 CLP, also be used to carry out  
22 statistical analysis to improve risk management measures, where requested by the Member  
23 State (the allowed use of the submitted information is discussed in section 7). The appointed  
24 bodies and poison centres (which are not necessarily the same entity, although in some  
25 Member States they are the same; see section 3.2 for more details), need to ensure the  
26 confidentiality of the information received.

27 The amended CLP Regulation, provides that ECHA specifies the harmonised format (i.e. Poison  
28 Centres Notification (PCN) format) for the preparation of information by economic operators.  
29 The PCN format also aims to facilitate the management and use of the submitted information  
30 by authorities and poison centres, who will receive the information and make it available in a  
31 database serving the emergency health response purpose.

32 Additionally, Annex VIII foresees ECHA to facilitate the submission of information. For this  
33 purpose, ECHA has made available a centralised Poison Centres Notification (PCN) portal,  
34 which is a submission system that could be used as an alternative to the national submission  
35 systems where available (it is at the discretion of each MS to indicate which system is to be  
36 used). More details are provided in section 6.

37 The deadlines for submitting the information are staggered and depend on the use type of the  
38 mixture (see section 3.4 for the definition of the different use types). Detailed information  
39 about timelines and deadlines is given in section 3.5.

40

### 41 **1.3 Aim of this guidance**

42 The aim of this guidance is to clarify and assist companies, appointed bodies and poison  
43 centres in the implementation of the new tasks and requirements outlined in Annex VIII to the

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<sup>6</sup> According to Article 2(18) of CLP “placing on the market means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.”

1 CLP Regulation.

2 This guidance provides information on:

- 3 • the scope of Annex VIII to CLP, i.e. for which type of mixtures the required information
- 4 has to be submitted;
- 5 • who should submit information in accordance with Annex VIII to CLP and by when;
- 6 • issues to consider when preparing for a submission of information;
- 7 • the use of the “Unique Formula Identifier” (UFI);
- 8 • the use of the harmonised European Product Categorisation System (EuPCS);
- 9 • details of the information required to be submitted;
- 10 • the use of the common XML harmonised reporting format;
- 11 • which changes or new information trigger the need for an update.

12 Note that, the IT tools provided to prepare and submit the information required by Annex VIII  
13 are referred to as the *submission* tools.

14

15

## 16 **1.4 Target audience of this guidance**

17 The main target audiences of this guidance are:

18

- 19 • companies placing certain hazardous mixtures on the market (i.e. that are classified as  
20 hazardous on the basis of their health or physical effects) and who are required to  
21 submit information relevant to poison centre activities.
- 22 • the Member States’ Competent Authorities and the appointed bodies who are  
23 responsible for receiving information on such hazardous mixtures which are being  
24 placed on the market.
- 25 • poison centres who are the end users of the submitted information for the purposes of  
26 formulating preventative and curative measures, in particular when providing an  
27 immediate health response<sup>7</sup>.

## 28 **1.5 Overview of the document**

29 This Guidance document is structured to present, after a general introduction, the main  
30 concepts which allow setting the scene and the framework for providing the required  
31 information. The main elements relevant to all the operators involved are then clarified before  
32 going into the details of the specific legal obligations. The obligations are then described by  
33 following the same section structure of Annex VIII.

- 34 • Section 1, presents the legal background, scope and target of this document in general  
35 terms.
- 36 • Section 2 provides a list of definitions and clarifies the main terms used throughout the  
37 Guidance.
- 38 • Section 3 provides relevant information for the reader to understand whether they have  
39 obligations under Annex VIII of CLP. Therefore, section 3 clarifies who is required to  
40 submit information and to whom, by when and which mixtures fall under the scope of  
41 Annex VIII.

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<sup>7</sup> It is to be noted that not in all Member States poison centres exist. Emergency service may be provide via different systems (see section 3.2.1 for further details).

- 1 • Section 4, presents the need to identify the mixture using a unique formula identifier,  
2 the harmonised European categorisation system (EuPCS) and the possibility to opt for a  
3 limited or a group submission. This section further explains the basic elements and  
4 options linked to the submission of information, which should be known before the duty  
5 holder starts preparing the submission.
- 6 • Section 5 describes in detail the information to be submitted to the appointed body, as  
7 required in Annex VIII.
- 8 • Section 6 presents the available tools and the system put in place to allow industry and  
9 authorities to comply with the legal obligations.
- 10 • Section 7 explains what happens after the submission. This includes a description of the  
11 possible uses of the information submitted to the appointed bodies, the requirement  
12 that the submitter must keep the information up to date, and which changes trigger the  
13 obligation to update the submission.
- 14 • Section 8 lists the main available additional supporting tools.

15

## 16 **1.6 Links to legislation other than CLP**

17 There is a network of EU legislation which relies on CLP classification (a detailed list of  
18 concerned legislation is available in the *Introductory Guidance on the CLP Regulation*<sup>8</sup>).

### 19 **1.6.1 REACH Regulation**

20 The provisions of Article 45 and Annex VIII to CLP are indirectly related to certain provisions of  
21 the REACH Regulation<sup>9</sup>.

22 In particular the safety data sheets (SDS), which are to be compiled following the  
23 requirements in Annex II to REACH, represent one of the main sources of information for the  
24 economic operator that is preparing a submission under Article 45 of CLP. The submitted  
25 information has to be consistent with the SDS and the SDS itself may be part of the  
26 submission to the appointed body<sup>10</sup>.

### 27 **1.6.2 Other legislation**

28 The EU legislation for biocides, plant protection products, cosmetics<sup>11</sup> and tobacco products are  
29 examples of EU legislation with data submission requirements that are partially overlapping  
30 with the harmonised information required under the scope of CLP Article 45 and as specified in  
31 Annex VIII.

32 As part of the biocides and plant protection products authorisation procedures (and which

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<sup>8</sup> All ECHA Guidance documents are available in the Support section of the ECHA website at:

<https://echa.europa.eu/guidance-documents/guidance-on-reach>.

<sup>9</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

<sup>10</sup> Please note, even when it is technically possible to attach the SDS to the submitted information, this will not replace the obligation to provide the information on the mixture. Nevertheless the SDS may be required for components of the mixture in certain cases (section 5.3 provides the details).

<sup>11</sup> Note that CLP does not apply to cosmetic products that are in the finished state intended for the final user (Article 1(5)(c)).

1 required before they are placed on the market), under the Biocidal Products Regulation<sup>12</sup> (BPR)  
2 and the Plant Protection Products Regulation<sup>13</sup> (PPPR), full information on the identification,  
3 composition and hazards of the mixture, including any mixture used in its composition, is  
4 required by the authorising Member State Competent Authority (MSCA).

5 Under the Tobacco Products Directive<sup>14</sup>, a notification of information on the identification,  
6 composition and hazards of e-liquid mixtures is required before placing on the market.

7 The Cosmetic Products Regulation<sup>15</sup> requires that responsible persons and, under certain  
8 conditions, the distributors of cosmetic products submit some information about the products  
9 they place on the market through a dedicated Cosmetic Products Notification Portal (CPNP).

10  
11 It remains at the discretion of each MSCA, for some of the respective legislative processes (i.e.  
12 where the legal text allows the competent authorities to do so), to assess and decide whether  
13 a procedure can be established in order to make information supplied under different EU  
14 legislations (as part of an obligatory authorisation or notification procedure) available to the  
15 appointed bodies under the scope of CLP, Article 45. However, information required by Annex  
16 VIII of CLP must be submitted to the appointed body/bodies by the duty holder regardless of  
17 whether the appointed body/bodies can use relevant existing information received through  
18 requirements under other EU laws. In addition, information submitted according to Article 45  
19 cannot be used for purposes other than those specified therein. Furthermore, the submission  
20 of the information under CLP must be provided in the harmonised format as outlined in Annex  
21 VIII.

### 22 23 **1.6.3 National legislation**

24  
25 It is to be noted that Annex VIII CLP is exhaustive, meaning that no additional information can  
26 be required under national legislation to that specified in Annex VIII for the purposes provided  
27 for under Article 45. However, certain aspects are left to the discretion of Member States, such  
28 as the establishment of acceptance criteria for submissions, the acceptance of information in  
29 languages other than official language(s), the application of fees before processing the  
30 submissions, reference to submission systems, etc.

31  
32 Nevertheless Member States may have in place submission requirements for substances or  
33 mixtures outside the scope of Article 45 for purposes other than those defined in that same  
34 Article. This can be regulated by national legislation and in general under a legal framework  
35 which is different from Article 45 and Annex VIII. For more information it is recommended to  
36 contact the responsible authority in the specific Member State.  
37

38 Note that in this Guidance Document the reference to specific Parts and Sections of Annex VIII  
39 to CLP is provided within square brackets [...].

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<sup>12</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

<sup>13</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

<sup>14</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

<sup>15</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

1

## 2. Abbreviations/definitions

2

| Standard term / Abbreviation | Explanation  |
|------------------------------|--|
| Annex VIII                   | Regulation (EU) 2017/542 amending CLP by adding an Annex on harmonised information relating to emergency health response   |
| Article 45                   | Article 45 of CLP  |
| BPR                          | Biocides Products Regulation. Regulation (EU) No 528/2012.   |
| CLP                          | Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.  |
| CPNP                         | Cosmetic Products Notification Portal  |
| Distributor                  | Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties (Article 2(20) of CLP).  |
| Downstream user              | Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities (Article 2(19) of CLP). |
| EAPCCT                       | European Association of Poisons Centres and Clinical Toxicologists   |
| EC                           | European Community   |
| ECHA                         | European Chemicals Agency  |
| EEA                          | European Economic Area   |
| EU                           | European Union   |
| EuPCS                        | European Product Categorisation System   |
| Formulator                   | Company that produces a mixture  |
| GPI                          | Generic Product Identifier   |
| Importer                     | Any natural or legal person established within the EU who is responsible for   |

|                  |  |
|------------------|--|
|                  | import (Article 2(17) of CLP), where the latter means the physical introduction into the customs territory of the EU (Article 2(16) of CLP).   |
| IUCLID           | International Uniform Chemical Information Database  |
| LD <sub>50</sub> | Median lethal dose   |
| MiM              | Mixture in a mixture   |
| Mixture          | A mixture or solution composed of two or more substances (Article 2(8) of CLP).  |
| MSCA             | Member State Competent Authority   |
| PCN              | Poison Centre Notification   |
| PPPR             | Plant Protection Products Regulation. Regulation (EC) No 1107/2009.  |
| REACH            | Registration, Evaluation, Authorisation of Chemicals. Regulation (EC) No 1907/2006.  |
| SDS              | Safety data sheet (see <i>Guidance on the compilation of safety data sheets</i> for more details)  |
| SME              | Small and medium enterprise  |
| Substance        | A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (Article 2(7) of CLP). |
| UFI              | Unique Formula Identifier (see section 4.2 of this Guidance)   |
| VAT              | Value added tax  |
| XML              | eXtensible Markup Language   |

1

## 2 3. Obligations

3 This section of the Guidance defines the general framework of the provisions of Article 45 of  
 4 CLP and Annex VIII. It clarifies who may play a role or has potential obligations related to  
 5 these provisions. It therefore explains which activities may trigger the obligation to submit  
 6 information under Article 45, which mixtures are affected and which bodies receive the

1 submitted information.

## 2 **3.1 Who is required to submit information?**

3 According to Article 45 of the CLP Regulation and as further specified in Annex VIII, importers  
4 and downstream users placing hazardous mixtures (meeting certain criteria, see section 3.3)  
5 on the market, are responsible for complying with the requirements established in Annex VIII  
6 to the CLP. 'Placing on the market' according to Article 2(18) of CLP '*means supplying or*  
7 *making available, whether in return for payment or free of charge, to a third party. Import*  
8 *shall be deemed to be placing on the market.'*

9 These duty holders are required to submit information as specified in the same Annex, that is  
10 relevant for formulating preventative and curative measures in the event of an emergency  
11 health response.

12 Therefore, the responsibility for submitting the information falls on the importers and  
13 downstream users. These are also referred to as duty holders or, in the context of CLP Article  
14 45 and Annex VIII as "submitters". The definitions of 'downstream user', 'importer' and other  
15 operators potentially part of the supply chain are given in Article 2 of the CLP Regulation and  
16 are consistent with the REACH Regulation. The same definitions are reported in section 2 of  
17 this Guidance. The *Guidance for Downstream Users* provides more information on the different  
18 roles and operators along the supply chain<sup>16</sup>.

19 As it will be clarified in this section, it is possible for a submission to be physically prepared  
20 and submitted by a third party. The use of a third party does not relieve the duty holder  
21 (importer or downstream user) from his obligations and responsibilities and his role of  
22 submitter.

23 In the sections below it is clarified which activities carried out by the different operators may  
24 confer to them the obligations to submit information to the appointed bodies according to  
25 Article 45.

26 Note: submission systems should foresee technical solutions allowing the submission of the  
27 information by a third party on behalf of the duty holder with two options: (i) preparation and  
28 submission of the information is outsourced and the actual duty holder has full access to  
29 information submitted on its behalf; and (ii) submission is prepared entirely by the third party  
30 who keeps the information confidential (even the duty holder would not have access to the  
31 information). This could apply in a wide range of scenarios, for example:

- 32 - mother company/head-quarter submitting on behalf of a subsidiary,
- 33 - distributor submitting on behalf of the supplier,
- 34 - non-EU supplier submitting on behalf of the importer,
- 35 - consultant.

### 36 **3.1.1 Activities leading to the obligation to submit information according to** 37 **Annex VIII** 38

39 The following activities carried out by an economic operator confer on them the obligation to

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<sup>16</sup> Note, the draft guidance reflects the current interpretation of the definition of downstream users and distributors. The interpretation of certain activities (in particular rebranding and relabelling, which are currently understood as distributors' activities) is under discussion at CARACAL level and may lead to the need to revise the draft Guidance accordingly (and therefore the identification of duty holders) before the final publication.



1 submit information related to an emergency health response:

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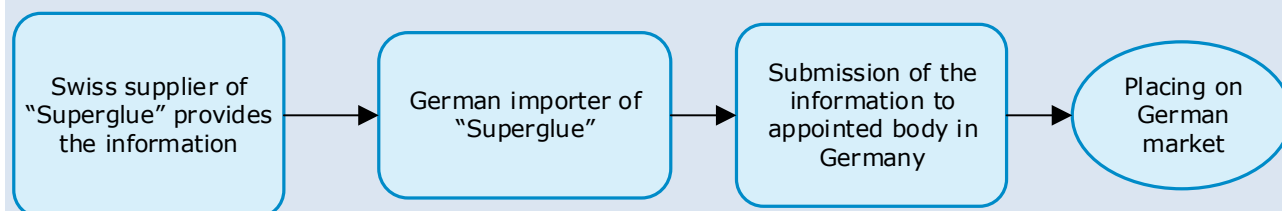
3 **IMPORT ACTIVITIES**

4 An economic operator that imports a hazardous mixture into the European Union, is an  
5 importer and therefore, they place the mixture on the market according to Article 2 of CLP and  
6 have the obligation to submit the information required by Annex VIII. The information must be  
7 submitted in the official language/s or any other language allowed by the Member State/s  
8 where the mixture is placed on the market. CLP applies to the European Economic Area (EEA),  
9 i.e. the 28 EU Member States and Iceland, Liechtenstein and Norway. This means that imports  
10 from Iceland, Liechtenstein and Norway does not constitute import for the purposes of CLP  
11 (unlike import from, e.g. Switzerland). Companies importing mixtures from outside the EEA  
12 must ensure that they have all the available information required for the submission of the  
13 harmonised information.

14 Details on the definition of importer are provided in section 2.1 of the *Guidance on*  
15 *Registration*<sup>17</sup>.

16 **Example 1:** EU operator importing from outside the EU, placing on the market in one EU  
17 country

18 A German company imports from Switzerland (a non-EU supplier) a mixture called Superglue  
19 and places it on the German market. This mixture is classified as hazardous for health effects.  
20 The German company needs to obtain from the Swiss supplier all the information needed to  
21 fulfil the Annex VIII requirements. The German importer will have to submit the information to  
22 the German appointed body.



23

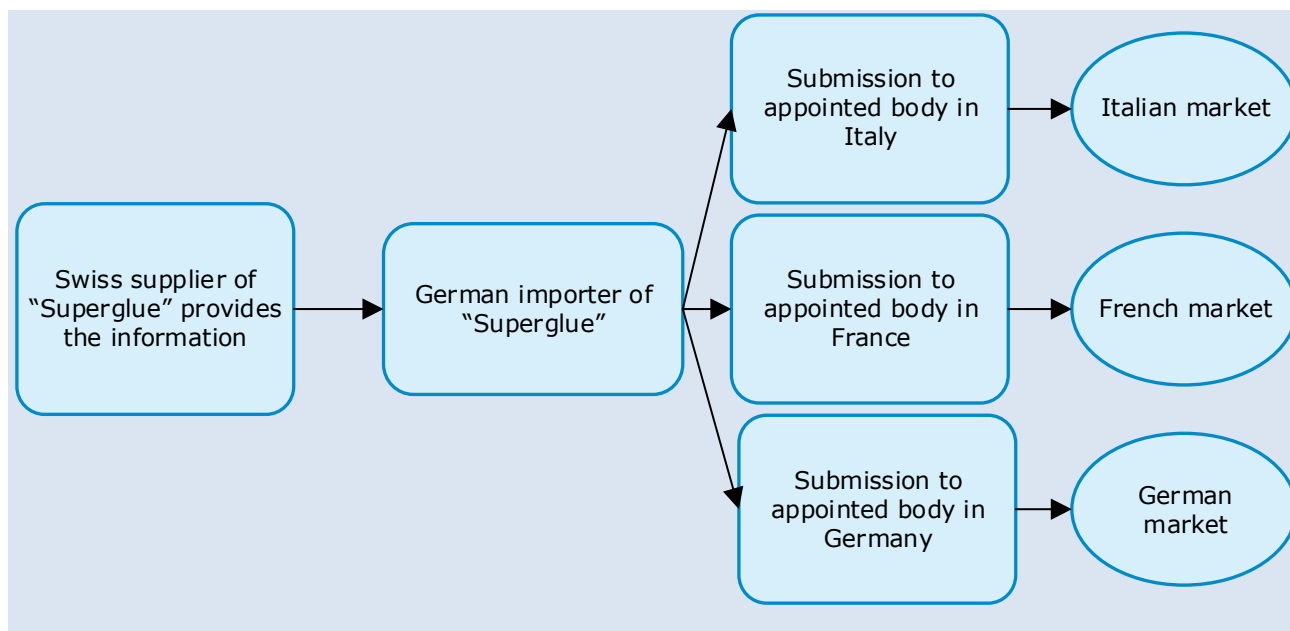
24

25 **Example 2:** EU operator importing from outside the EU, placing on several EU markets

26 If Superglue (see example above) is then intended to be placed on the market in multiple  
27 countries, the German importer (from example 1) will have to submit the information to the  
28 appointed bodies of the relevant EU countries before placing the mixtures on the market in  
29 those countries.

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<sup>17</sup> Note that this section refers specifically to the obligations under the REACH Regulation. Nevertheless, the definition of importer and the examples provided are relevant for the purposes of Annex VIII to CLP.



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4 The imported mixture may be used at the first place of import by the importer themselves, or  
5 may be imported in Member State A and subsequently placed on the market also in Member  
6 State B. Since import is deemed to be "placing on the market", a submission is required in  
7 both Member States A and B. The submission obligation applies to the importer according to  
8 the use type of the mixture (industrial, professional or consumer use, as it will be explained  
9 later in section 3.4).

10 Ideally, the non-EU supplier of the hazardous mixture discloses the entire mixture formulation  
11 information to their customer (the EU importer), so that the latter can make their submission.  
12 Nevertheless, there are cases where complete information is not available or not given  
13 because of confidentiality reasons. Alternative ways to work around this problem are described  
14 in section 4.2.5.

15 In any case it is ultimately the responsibility of the EU importer to demonstrate that it complies  
16 with Annex VIII and thus to gather and submit the information required by Annex VIII.  
17 Therefore, it may be necessary to put additional effort in the communication with the non-EU  
18 supplier in order to obtain the necessary information. The duty holder may want to document  
19 such efforts for enforcement purposes to justify cases where the provided information on  
20 components of a mixture is limited to the information obtained in an SDS.

21

## 22 **FORMULATION ACTIVITIES**

23 A company that produces a mixture is a formulator, and is covered by the definition of  
24 downstream user under the CLP Regulation.

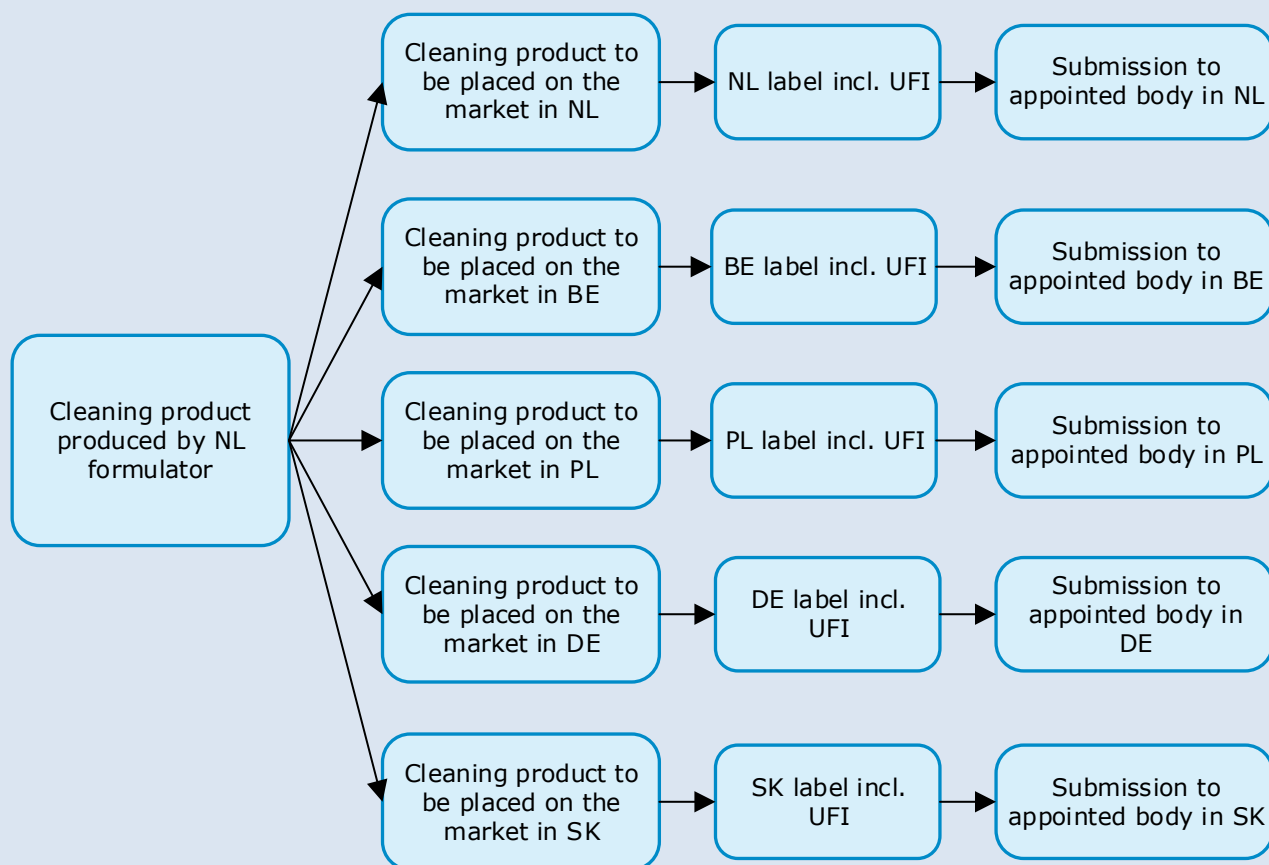
25 Therefore, any economic operator that formulates and places on the market a hazardous  
26 mixture meeting certain criteria (see section 3.3) has the obligation to submit the information  
27 in accordance with Annex VIII. The submission has to be made in all the Member States where  
28 the mixture is placed on the market in the official language of the relevant Member State  
29 (unless the Member State concerned provides otherwise, see below for more details).

30 A company formulating a mixture on behalf of another company/brand name is also a  
31 formulator (a toll formulator) and thus a downstream user. A toll formulator in the EU is the  
32 entity that first supplies and makes the mixture available on the market, even though the toll  
33 formulator does not itself own the product or the intellectual property rights.

1 The toll formulator thus has the obligations associated with CLP Article 45. It may, however, be  
 2 contractually agreed<sup>18</sup> that it is the company owning the mixture who submits the information  
 3 relevant to the appointed bodies. In practice, the company which actually produces the  
 4 mixture should have the relevant compositional information required by Annex VIII. This is the  
 5 company in the position to respond to any request for additional information from the  
 6 authorities (in the cases foreseen by the legislation, see section 7). If the company owning the  
 7 mixture simply stores and places the mixture on the market, they would not have any  
 8 submission obligations themselves, as they would be a distributor. If the same company  
 9 subsequently themselves uses that mixture, for example in the formulation of another one, it  
 10 would be a downstream user and would have submission obligations.

11 **Example 3:** Mixture placed on the market in several Member States

12 A company in the Netherlands formulates a cleaning product under the company brand name.  
 13 The cleaning product is classified and labelled as flammable and irritating to the skin; it is sold  
 14 in the Netherlands as well as to distributors in Belgium, Poland, Germany and Slovakia. The  
 15 Dutch formulator must thus submit information in accordance with CLP Article 45 and Annex  
 16 VIII to the appointed bodies in these five countries in their official language or in the  
 17 language(s) as requested by the Member State in which the mixture is placed on the market.  
 18 In case the mixture is placed on the market in different packaging in the different Member  
 19 States, the information of the packaging relevant in each Member State must be given in the  
 20 specific submissions.

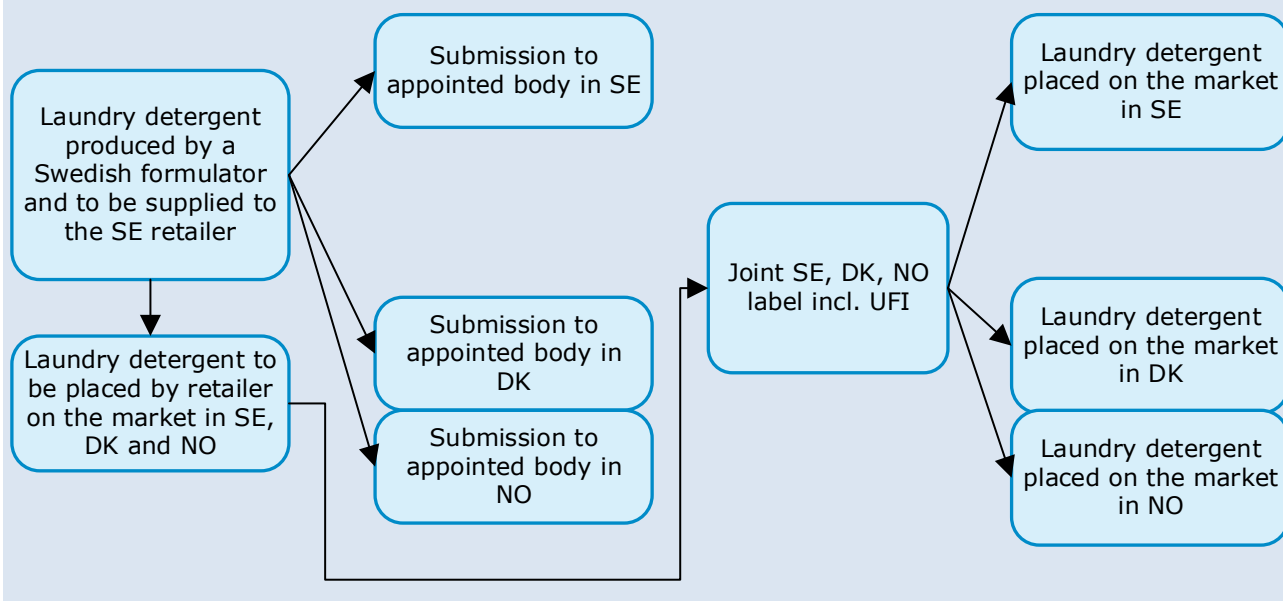


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18 More information available from the ECHA Factsheet '[Information for parties involved in contractual arrangements for toll manufacturing](#)'.

1 **Example 4:** Formulation, mixture placed on the market in several Member States

2 A formulator in Sweden formulates a laundry detergent for consumer use and sells it to a large  
3 Swedish-owned retailer selling the product in Sweden, Denmark and Norway. The laundry  
4 detergent is classified and labelled as causing severe eye damage. The relevant information  
5 must be submitted by the formulator to the appointed body in Sweden. Additionally, a  
6 submission needs to be done by the formulator in those Member States where the retailer  
7 (provided that the retailer fulfils the conditions to qualify as a distributor in accordance with  
8 Article 2(20) CLP) intends to sell the product (as Norway has also implemented the CLP  
9 Regulation though the EEA agreement, the information must also be submitted to the  
10 appointed body in Norway). The label for the laundry detergent includes (in this example) all  
11 three languages.



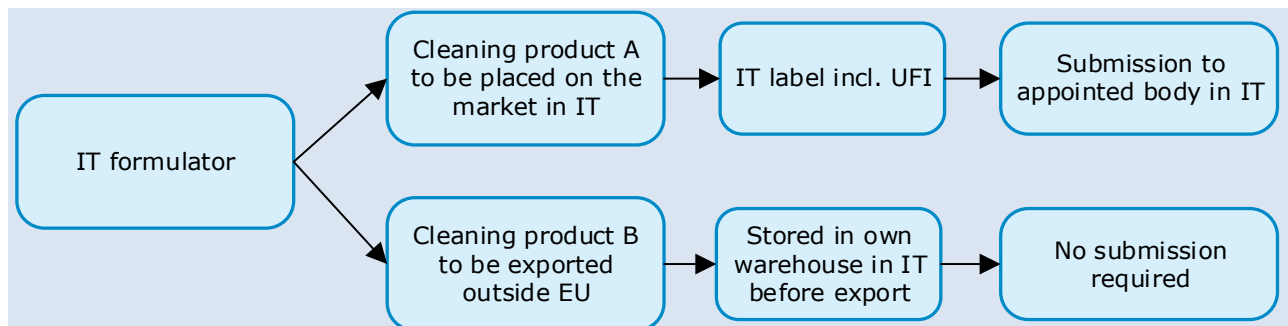
12  
13 A company that formulates a mixture but does not place it on the European Union market and  
14 only formulates with the intention of exporting does not have the obligation to make the  
15 submission<sup>19</sup>. If the product is stored in a temporary warehouse before being exported outside  
16 the EU, this may qualify as placing on the market and therefore the obligations according to  
17 Annex VIII apply. This would be the case if, for example, the formulator makes available the  
18 mixture, whether in return for payment or free of charge, to a third party which stores the  
19 mixture in the warehouse before delivering it to a non-EU company. If the mixtures are stored  
20 by the same DU that formulates them in a warehouse, there would be no obligations to submit  
21 information<sup>20</sup>.

22 **Example 5:** Formulation, mixture to be placed on the market outside EU

23 A formulator in Italy formulates two lubricant products (product A and product B) which are  
24 classified for aspiration toxicity. The lubricant B is exported to Turkey, i.e. out of the EU. As  
25 the data submission requirements under the scope of CLP Article 45/Annex VIII only applies in  
26 the EU Member States (and in countries under the EEA agreement) there are no obligations to  
27 submit data for product B.

<sup>19</sup> Please, note that other obligations under CLP may also apply.

<sup>20</sup> Please note that CLP does not apply to mixtures which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit (Article 1(2)(b)).



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### **REPACKAGING ACTIVITIES**

4 A company that repacks/refills (transfers from one container to another) a mixture and either  
5 keeps or modifies the content of the original label is performing activities that qualify as  
6 downstream user activities according to CLP. This company is therefore a duty holder for the  
7 purposes of Annex VIII. This is the case even if the company does not perform any other  
8 activity with the mixture (e.g. no changes in the composition). As the company is placing a  
9 mixture on the market which is chemically identical to the one of their supplier, they may  
10 decide to request the supplier to make the submission on their behalf (a contractual  
11 agreement would be needed). Alternatively, the company that repackages mixtures must  
12 make a separate submission (possibly using the same UFI as the supplier). In both cases the  
13 company placing the mixture on the market (i.e. in the new package) remains responsible for  
14 the submitted information (i.e. the duty holder) even if in the first case the entity making the  
15 actual submission would be a different party (i.e. the supplier).

#### 16 3.1.1.1 Obligations and supply chain

17 The fulfilment of the obligation on importers and downstream users to submit the information  
18 in all the Member States where the mixture is placed on the market requires consideration of  
19 the full supply chain, i.e. any distribution step is to be taken into account. Distributors  
20 normally supply the product further down the supply chain possibly in different Member States  
21 and changing trade names and/or labels.

22 It is the legal obligation of the importer or downstream user as duty holder to submit the  
23 information in all the Member States where the product is placed on the market, either directly  
24 by the importer or downstream user or by the distributor. The duty holder has also to make  
25 sure that all trade names under which the mixture is placed on the market are covered by a  
26 submission to the relevant Member State. In practical terms this limits the possibility of data  
27 gaps and is beneficial for the poison centre, the trade name often being the most  
28 straightforward means of identification of a product.

29 It is to be noted that the formulator should expect collaboration from their distributors to  
30 receive information on where the product is placed on the market. In order to cover for  
31 potential distribution steps in the supply chain, it is strongly advised for duty holders to set up  
32 a contractual agreement with their distributors specifying that the distributor will inform their  
33 upstream supplier of the Member States where they place the product on the market, potential  
34 product name changes and any other relevant information. The upstream supplier (duty  
35 holder) can then include this information in their submission. Alternatively, if the distributor  
36 does not want to disclose this information, for example for reasons of confidentiality, the  
37 contract may stipulate that the distributor will submit the relevant information themselves.

38

#### 39 **3.1.2 Activities not leading to submission obligations according to Annex VIII**

40 Companies in the supply chain of a mixture may have roles other than a downstream user or

1 an importer and may not be required to submit the information according to Article 45 and  
2 Annex VIII. An example of an activity which does not lead to such an obligation is one that  
3 involves distribution only. If a company only stores and places on the market a mixture,  
4 without undertaking any other activity on the mixture, it is considered a distributor and does  
5 not need to submit the information.

6 However, distributors may also play an important role in the obligation placed on DUs and  
7 importers to make information available to poison centres for the purposes of their work  
8 (please see Appendix 1 to the *Guidance for Downstream Users* for more information on the  
9 role of the distributor). This is relevant, in particular, for distributors that change the name of  
10 the mixture and/or sell the mixture in Member States other than the Member State where the  
11 downstream user or importer has supplied it. In these cases, distributors are encouraged to  
12 communicate with their supplier to inform about the new names and/or the Member States  
13 where they place or intend to place the mixture on the market in order to facilitate the duty  
14 holders in fulfilling their obligations. The supplier can then submit the information to the  
15 respective appointed bodies in the required language. Alternatively, the distributor may  
16 voluntarily decide to submit the information as requested by Annex VIII to the appointed body  
17 of the Member State on behalf of the formulator where they place the mixture on the market,  
18 but there is no obligation for them to do so. In this case the parties should agree via  
19 contractual agreement that the information is submitted by the distributor.

20 Please note, however, that in the case of distribution the upstream supplier is still a duty  
21 holder for the distribution step, as the distributor performs their activity on behalf of the  
22 upstream supplier. As stated above, in order for upstream suppliers to be able to fulfil their  
23 legal obligations it is strongly advised that a contractual agreement is set up between the  
24 upstream supplier and the distributor stipulating any requirements for information sharing or  
25 submission of information by distributors themselves.

26

## 27 **RE-BRANDING/RE-LABELLING ACTIVITIES**

28 A company which re-brands and re-labels a mixture and places it on the market without  
29 performing any other activities, is not a downstream user according to CLP<sup>21</sup> and therefore  
30 does not have the obligation to submit the Annex VIII information. Such activities fall under  
31 the definition of distributor's activity<sup>22</sup> and hence the legal obligation to submit information for  
32 this step in the supply chain falls again on the upstream duty holder as explained in sections  
33 3.1.1.1. and 3.1.2.

34 The company which re-brands or re-labels is recommended to communicate with the supplier  
35 in order to facilitate the submission of the information to the relevant appointed bodies in  
36 accordance with Annex VIII by the duty holder (the upstream downstream user or importer).  
37 The rationale behind this is that if a product name changes and no new submission is made,  
38 the poison centre may not be able to retrieve information based on the product name given by  
39 a caller or the poison centre might be confused by the difference between the UFI and the  
40 trade name that it has on record.

41 As with re-packaging activities, the re-branding or re-labelling company could alternatively  
42 agree via contractual agreement with their supplier and make themselves a submission  
43 containing the additional product names/brands under which the product will be placed on the

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<sup>21</sup> Note, the draft guidance reflects the current interpretation of the definition of downstream users and distributors. The interpretation of certain activities (in particular rebranding and relabelling, which are currently understood as distributors' activities) is under discussion at CARACAL level and may lead to the need to revise the draft Guidance accordingly (and therefore the identification of duty holders) before the final publication.

<sup>22</sup> See the *Guidance for downstream users* for more details.

1 market.

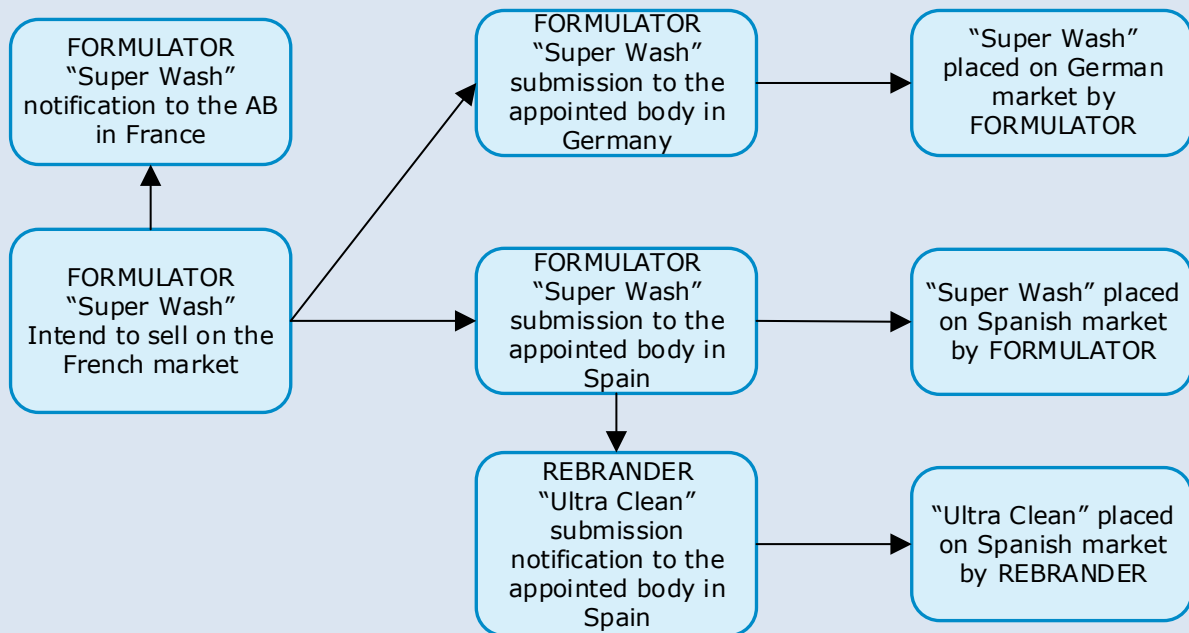
2 **Example 6:** Submission made by re-labelling company placing on a new market

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4 A company in France formulates and intends to sell "Super Wash" on the French market. The  
5 mixture is labelled hazardous for human health and the formulator has submitted all relevant  
6 information to the appointed body in France.

7 The company decides to open up markets and to sell the same product in Spain and Germany.  
8 The company re-labels the product, keeping the brand name "Super Wash", and submits the  
9 relevant information to the Spanish and German appointed bodies.

10 A customer (distributor) in Spain decides to sell this product (with no changes in the  
11 composition) with their own brand "Ultra Clean". As the distributor does not want to disclose to  
12 their upstream supplier the fact that they place the same mixture on the market under a  
13 different name, the distributor submits the required information to the Spanish appointed  
14 body. This is in line with the contractual agreement drawn up between the distributor and the  
15 formulator.



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**Table 1: Overview of operators and activities triggering (or not triggering) obligations under Article 45 and Annex VIII**

| Activity                                     | Operator | Legal obligation to submit information? (duty holder/submitter)? | Why?  | Obligations along the supply chain  | Options  |
|--|----------|--|---|---|--|
| Import                                       | Importer | Yes  | Legal text  | The mixture may be placed on the market in different Member States by distributors, who may possibly rebrand or relabel the product. It is the DU/I's obligation to submit the information in each Member State where their distributors place the mixture on the market and to cover the different brands/trade names. | A company may rely on their supplier (e.g. mother company) or other company to make the submission on their behalf - this submission would include their product details. They remain duty holder (if applicable, i.e. re-packager and re-filler) but they are not the legal entity submitting the information in the submission system. Contractual agreement may be needed between the duty holder and the company preparing the submission on its behalf. This should address all possible scenarios: update responsibilities, access to the file, etc... |
| Formulation                                  | DU       | Yes  | Legal text  |   |  |
| Re-packaging                                 | DU       | Yes  | Activity is a use according to CLP and REACH (Transfer into new/different containers). See also ECHA <i>Guidance for downstream users</i> . |   |  |
| Re-filling (see also above for re-packaging) | DU       | Yes  | Activity is a use according to CLP and REACH (Transfer into new/different containers). See also ECHA <i>Guidance for downstream users</i> . |   |  |



|                  |                        |     |   |     |   |
|------------------|------------------------|-----|---|-----|---|
| Toll formulation | DU                     | Yes | Toll formulators are downstream users. See ECHA <i>Guidance for downstream users</i> .  |     |   |
| Distribution     | Distributors           | No  | Legal text  | n/a | Advice to set up contractual agreement between distributor and supplier stipulating that the distributor must either:   |
| Retail           | Distributor (retailer) | No  | Storage/placing on the market of mixtures to consumers without performing any activity qualifying as DU activity. See also ECHA <i>Guidance for downstream users</i> . The distributor uses the same UFI as the supplier/duty holder. | n/a | <ul style="list-style-type: none"> <li>- inform the supplier of the change of name and Member State(s) where the product is placed on the market.</li> <li>- submit the information on behalf of the supplier (who remains the duty holder).</li> </ul> |

|                           |             |    |   |     |  |
|---------------------------|-------------|----|---|-----|--|
| Re-branding <sup>23</sup> | Distributor | No | Actor who applies his own brand to a product that somebody else has manufactured and places the product on the market. The activity is not considered as a DU activity.<br>See also ECHA <i>Guidance for downstream users</i> . | n/a |  |
| Re-labelling              | Distributor | no | Actor that affixes the label to a mixture that somebody else has already labelled. The activity is not considered as a DU activity.<br>See also ECHA <i>Guidance for downstream users</i> .                                     | n/a |  |

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<sup>23</sup> Note, the draft guidance reflects the current interpretation of the definition of downstream users and distributors. The interpretation of certain activities (in particular rebranding and relabelling, which are currently understood as distributors' activities) is under discussion at CARACAL level and may lead to the need to revise the draft Guidance accordingly (and therefore the identification of duty holders) before the final publication.

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|   |   |    |            |   |  |
|---|---|----|------------|---|--|
| Commercial representative (=consultant) | The commercial representative is assigned the task to submit in the name and on behalf of the duty holder (DU, importer). | No | Legal text | Need for a contractual agreement (mandate). |  |
|---|---|----|------------|---|--|

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## 3.2 Who receives the information?

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The company that is required to submit the information according to Annex VIII, has to make sure that this information is submitted to the appointed bodies of all the Member States where they place the mixture on the market. This includes the Member States where their mixture is sold via their distributors.

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The information should eventually be made available to the poison centres and the personnel dealing with emergency responses in the Member State where the mixture is placed on the market.

### 3.2.1 Member States' appointed bodies

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Article 45(1) of CLP establishes that each Member State must appoint a body (or bodies)<sup>24</sup> responsible for receiving the information submitted by importers and downstream users related to mixtures placed on the market that are classified as hazardous based on their health or physical effects. The national appointed body or bodies may be a Member State Competent Authority on CLP (MSCA), a poison centre, a National Health Authority or another body appointed by the MSCA. The appointed body in a given Member State must have access to all the submitted information in order to carry out their tasks related to emergency health response. In those cases where the appointed body is not the poison centre, the national appointed body should make the submitted information available to the poison centres.

20 A list of national appointed bodies is available at the ECHA Poison Centre website:

21 <https://poisoncentres.echa.europa.eu/>

22 The appointed bodies must ensure that the information received is kept confidential and is only  
23 used for the purpose of Article 45(1) and (2) of CLP. See section 7.3 for further information  
24 about the use of the submitted information.

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## 3.3 About what has information to be submitted?

27 This subsection provides guidance on the scope of Article 45 and Annex VIII to CLP. It clarifies  
28 for which mixtures there is an obligation to submit information to the appointed bodies  
29 according to the legal text, which mixtures are exempted from the obligation and which  
30 information could be submitted on voluntary basis.

31 It is important to clarify that Article 45 and Annex VIII apply to *mixtures*. Substances<sup>25</sup> placed  
32 on the market on their own, either classified or not, are excluded from the obligation to submit  
33 information according to Article 45 of CLP.

34 Sections 4 and 5 below provide more information on the content of the submission as well as  
35 special situations including limited information requirements.

36

### 3.3.1 Which mixtures require information to be submitted?

37 Annex VIII requires the submission of information about mixtures that are placed on the EU  
38

---

<sup>24</sup> Please note that the legal text (Article 45) foresees the possibility for a Member State to appoint more than one body, although it is not often occurring in practice. In subsequent text of the guidance all references are made to singular appointed body for readability purposes.

<sup>25</sup> Definitions in Article 2 of CLP apply. See Section 2 of this Guidance for a full list of relevant terms and definitions.

1 market and classified as *hazardous* based on their *health* or *physical* effects. It means that all  
2 mixtures meeting any of the the criteria defined in Part 2 and Part 3 of Annex I to CLP fall  
3 under the scope of Article 45 and Annex VIII.

#### 4 3.3.1.1 General exemption from CLP Regulation and Article 45

5 Pursuant to Article 1(2) of CLP, the Regulation (and therefore Annex VIII provisions) does not  
6 apply to:

7

8 • “radioactive substances and mixtures [...]”;

9 • “substances and mixtures which are subject to customs supervision, provided that they  
10 do not undergo any treatment or processing, and which are in temporary storage, or in  
11 a free zone or free warehouse with a view to re-exportation, or in transit”;

12 • mixtures used in scientific research and development , provided they are not placed on  
13 the market and they are used under controlled conditions in accordance with EU  
14 workplace and environmental legislation;

15 • waste; and

16 • certain mixtures in the finished state, intended for the final user:

17 ○ medicinal products,

18 ○ veterinary medicinal products,

19 ○ cosmetic products,

20 ○ medical devices which are invasive or used in direct physical contact with the  
21 human body, and in vitro diagnostic medical devices, and

22 ○ food or feeding stuffs.

23 Among the mixtures which fall under the scope of the CLP Regulation, those classified for  
24 environmental hazards *only* are outside the scope of Article 45 and information according to  
25 Annex VIII does not need to be submitted. Also mixtures which are subject to supplemental  
26 labelling requirements according to Part 1 and 2 of Annex II to CLP but are not themselves  
27 classified for health or physical hazards are not subject to submission requirements.

28

#### 29 3.3.1.2 Exemptions from the obligation to submit information under Annex VIII

30 The following mixtures, even if falling under the scope of the CLP Regulation and classified for  
31 health or physical hazards, are exempted from the obligation to submit information. This is  
32 specified in section 2, Part A of Annex VIII:

33 • mixtures for scientific research and development (as defined in Article 2(30) of  
34 Regulation (EC) No 1272/2008),

35 • mixtures for product and process oriented research and development (as defined in  
36 Article 3(22) of Regulation (EC) No 1907/2006),

37 • mixtures classified only for one or more of the following physical hazards:

38 ○ (1) gases under pressure (as defined in Annex I, 2.5 of Regulation (EC) No  
39 1272/2008);

40 ○ (2) explosives (unstable explosives and Divisions 1.1 to 1.6) (as defined in  
41 Annex I, 2.1 of Regulation (EC) No 1272/2008).

42

#### 43 3.3.1.3 Voluntary submission of information

44 For mixtures which are not subject to submission obligations (see sections 3.3.1), submission

1 may be done on a voluntary basis.

2 In fact, although it is not mandatory, submission of relevant information about mixtures not  
3 classified on the basis of their health or physical effects is encouraged, to facilitate the  
4 appointed bodies and poison centres' activities. A mixture, although not classified as hazardous  
5 on the basis of health or physical effects, may be harmful in certain poisoning cases (i.e.  
6 babies, pre-existing pathological condition, etc). The availability of information even on such  
7 mixtures would significantly decrease possible uncertainties in case of emergency calls and  
8 therefore it could support a quicker and more effective identification or curative measures.

9 Mixtures for which submission of information is not required can be also used in the  
10 formulation of other classified mixtures (mixture in a mixture or MiM) generating potential  
11 gaps in the knowledge of mixture composition. When the duty holder does not know the  
12 composition of the MiM, it would rely on the SDS of that mixture, which does not provide all  
13 the relevant information. The supplier could, following a voluntary submission, communicate  
14 the compositional information to the customer via the UFI while ensuring the protection of  
15 confidential business information. Lack of detailed compositional information could hamper the  
16 medical advice in the event of an emergency or in the establishment of risk management  
17 measures by authorities. In cases where the appointed body and poison centre do not have  
18 access to the full composition of the mixtures, the response in case of an emergency could  
19 potentially lead to incorrect medical advice and /or overtreatment. A voluntary submission of  
20 the mixture to be used in another mixture might allow the emergency responder to retrieve all  
21 the necessary information.

22

### 23 3.4 Use types

24 The identification of the correct use type for the mixture for which submission is made is  
25 important as it defines the information requirements and the deadline (see section 3.5 and  
26 Figure 1 below) by which the obligations have to be fulfilled. Annex VIII, Part A, Section 2.4  
27 defines three types of use as follows:

28

- 29 - **Mixture for consumer** use means a mixture intended to be used by consumers;
- 30 - **Mixture for professional** use means a mixture intended to be used by professional  
31 users but not at industrial sites;
- 32 - **Mixture for industrial** use means a mixture intended to be used at industrial sites  
33 only.

34

35 The use types are based on the concept of *end-use*. End-use means the use of a mixture, as a  
36 last step before the end-of-life of the mixture, namely before the mixture (or each of its  
37 components) is emitted to waste streams or the environment, is included into an article or is  
38 consumed in a process by reaction during use (including intermediate use as defined by the  
39 CLP Regulation)<sup>26</sup>. In applying this approach to mixtures, this means that the use of a mixture  
40 continues when it is incorporated in another mixture until it reaches its end-of-life stage.

41 Therefore, if a mixture formulated to be used in an industrial setting ("original mixture") is  
42 subsequently also integrated by a downstream user into a mixture for professional or  
43 consumer use ("final mixture"), then the original mixture should be considered to be for  
44 professional or consumer end-use and the corresponding information requirements must be  
45 fulfilled and the deadline met. When exposed to the final mixture, professionals or consumers

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<sup>26</sup> Adapted from the ECHA Guidance R.12 *Guidance on Information Requirements and Chemical Safety Assessment* which is available at <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>.

1 come into contact with the original mixture which is contained in the final mixture. For poison  
2 centres to be able to provide an appropriate emergency health response, sufficiently detailed  
3 information on the final mixture and its components needs to be available.

4 While upstream formulators may not have a complete and detailed overview of all the final  
5 mixtures in which their original mixture (as a MiM) have been incorporated into, they often do  
6 have the general knowledge of whether their mixtures are incorporated into mixtures for  
7 professional or consumer use. In case of uncertainty, the company preparing the submission  
8 for the original mixture should, where possible, make an effort to gather such information. If  
9 new information about the use type of the original mixture becomes available after the  
10 submission, the information submitted under Annex VIII needs to be updated accordingly if  
11 needed.

12 Note that the submission should reflect the use type of the original mixture as placed on the  
13 market by the submitter, as well as the final mixtures where it may end up in (see section  
14 5.2.3). However, when original mixtures end up in final mixtures which are not subject to  
15 submission obligations (e.g. the final mixture is a cosmetic product, or the final mixture is not  
16 classified for health of physical hazards), the uses of these final mixtures do not need to be  
17 considered for submission purposes. For example, if a mixture for industrial use ends up in a  
18 final mixture classified for environmental hazards only, a submission for mixtures for industrial  
19 use suffices (relevant deadline and option for limited submission).  
20

## 21 **3.5 Timelines**

### 22 **3.5.1 Dates of application**

23 The deadline for the submission of the information following the new requirements set by the  
24 amended CLP Regulation<sup>27</sup> will apply in a stepwise manner, according to the use type of the  
25 mixture i.e. consumer, professional or industrial use (see section 3.4). Importers and  
26 downstream users placing mixtures on the market not notified already under national  
27 legislation must comply with Annex VIII of the Regulation from the following dates:

- 28 • Mixtures for consumer use: from 1 January 2020.
  - 29 • Mixtures for professional use: from 1 January 2021.
  - 30 • Mixtures for industrial use: from 1 January 2024.
- 31

32 Figure 1 below illustrates by means of an example how to identify the applicable deadline and  
33 information requirements on the basis of the use type.

34 Where a mixture has several types of use, the earlier corresponding deadline applies and  
35 related requirements must be met. For instance, in the case of a glue classified as hazardous  
36 for health effects, and placed on the market for both consumer and professional use, the  
37 earlier deadline of 1 January 2020 will apply.

38 Note that by 1 January 2025 a submission must be made for all mixtures on the market  
39 according to the harmonised Annex VIII requirements (see also section 3.5.2).

40 Before these dates, mixtures continue to be subject to existing national requirements and duty  
41 holders should contact the appointed body in the country of interest for further information. A  
42 list of national appointed bodies is available at the ECHA Poison Centre website:

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<sup>27</sup> It is amended by Commission Regulation (EU)2017/542 by adding Annex VIII.

1 <https://poisoncentres.echa.europa.eu/>

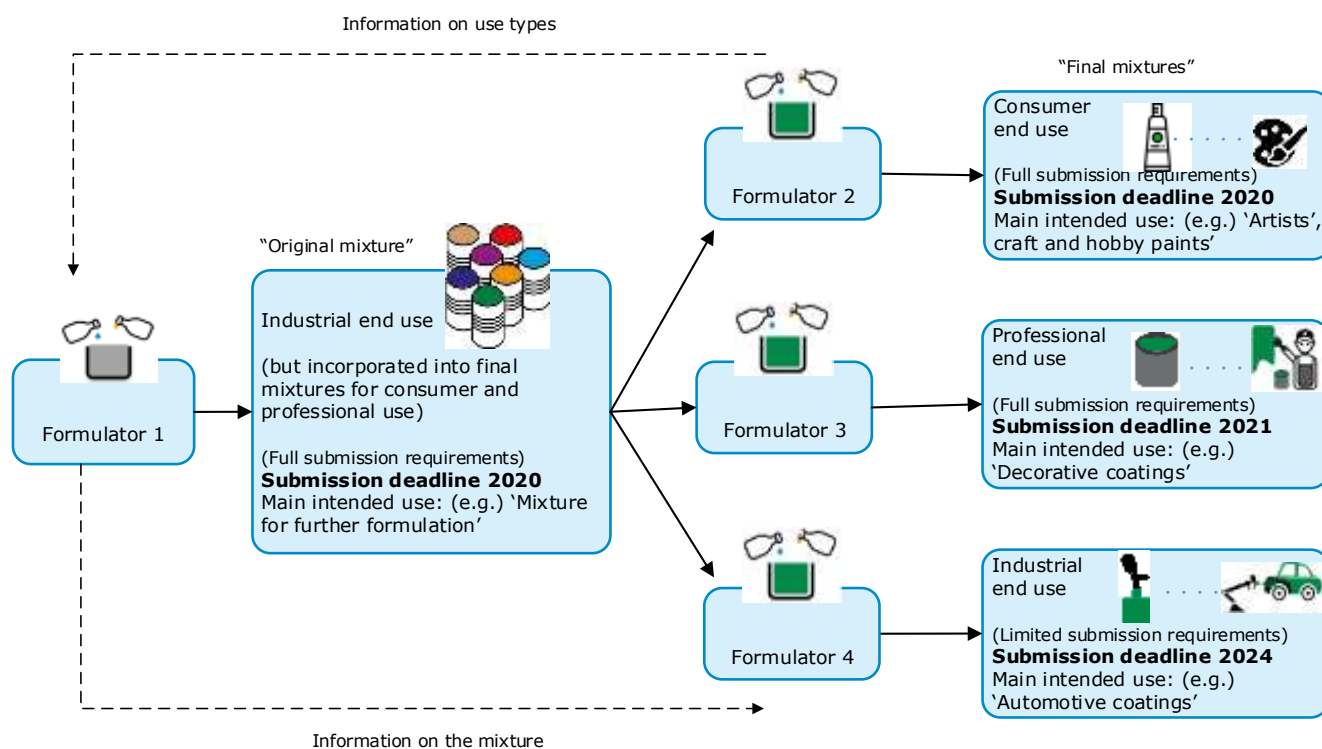
2 Companies can decide to make a submission in accordance with Annex VIII before the dates  
3 mentioned above. However, in that case it should be verified with the relevant appointed body  
4 whether it already accepts submissions in the new format and whether this releases from the  
5 duty to make a parallel submission according to national provisions being in force until the  
6 date of applicability of Annex VIII.

7 Independently from any obligation under Annex VIII, obligations at national level (established  
8 under different legal frameworks and for purposes other than those established by Article 45)  
9 may also remain valid and may still need to be fulfilled regardless of the submission having  
10 been made under the new format.

11

12 **Figure 1: Identification of information requirements and deadline according to the**  
13 **use type**

14



15  
16

17

18

### 19 3.5.2 Transitional period

20 If a company has already submitted information relating to hazardous mixtures to an  
21 appointed body in accordance with Article 45(1) before the relevant date of applicability (i.e.  
22 according to the notification requirements existing at that time in any given Member State),  
23 there is no obligation to comply with Annex VIII until 1 January 2025 (transitional period),  
24 except in cases where there is a need to provide updated information (see below).

25 If the company intends to keep placing the same mixture on the market after 1 January 2025,  
26 they will have to provide a new submission in full accordance with Annex VIII of the Regulation



1 by that date. As of 1 January 2025 'old' submissions will be considered as 'archived' and not  
2 relevant with regards to Annex VIII. Thus, operators must ensure that a new submission is  
3 made in due time to allow them to continue placing the mixture on the market.

4 However, if there is a change in the mixture composition, product identifier (including UFI) or  
5 toxicological properties during the transitional period (i.e. after the relevant date of application  
6 mentioned in section 3.5.1 and before 1 January 2025) the duty holder is required to submit  
7 information concerning the changed mixture in accordance with Annex VIII before it is placed  
8 on the market (relevant information is provided in section 7 of this Guidance, where the needs  
9 for an update are discussed).

10  
11 A submission made under the existing national system(s) according to the existing definition of  
12 end use in a specific Member State (definitions of end use types may have been implemented  
13 differently in different Member States before the entry into force of Annex VIII) remains valid.  
14 The company does not need to comply with Annex VIII before the end of the transitional  
15 period if their actual end use type does not change even if the definitions of use for their  
16 mixture has changed.

17  
18

## 19 **4. General submission requirements**

20 This section of the Guidance introduces the obligations under Article 45 and the main elements  
21 concerning the submission of information as required by Annex VIII. Once the duty holder and  
22 their need to fulfil the obligations are identified as explained in section 3, certain concepts and  
23 possible ways forward should be understood before starting to prepare the submission. These  
24 are explained in this section.

25

### 26 **4.1 Overview**

27 A company placing a mixture on the market and subject to obligations under Article 45, has to  
28 provide the information required by Annex VIII to the appropriate appointed body in the  
29 Member States where the mixture is placed on the market. The submission must be made  
30 either directly to the national appointed body or (when allowed by the Member State) using  
31 the PCN portal at ECHA, and must be submitted by electronic means in a harmonised XML  
32 format provided by ECHA (see section 6 for the details on the available submission tools).

33 In order to improve the emergency response and facilitate the work of poison centres in  
34 general, a new more specific means for the unique identification of a mixture has been  
35 introduced by Annex VIII. Labels for mixtures placed on the market will generally be required  
36 to carry a Unique Formula Identifier (UFI)<sup>28</sup>. A UFI enables rapid and unambiguous  
37 identification of the information submitted on the mixture by any poison centre called upon to  
38 provide advice on dealing with a poisoning incident. Information on the generation and use of  
39 UFIs is provided in section 4.2.

40 Duty holders are also required to provide information on the main intended use of the mixture  
41 (e.g. detergent, construction product, plant protection products, etc.) which is important for  
42 both emergency response and statistical analysis purposes. In order to facilitate the  
43 transmission of such information and its use by the receiving bodies, a European Product  
44 Categorisation System (EuPCS) has been developed. Section 4.3 illustrates the concept and

---

<sup>28</sup> Part A, point 5.3 of Annex VIII includes derogations for mixtures for industrial use only and mixtures not packaged (see section 4.2 for more details).

1 provides relevant links.

2 The company which is required to make the submission should be aware that besides the  
3 standard submission, Annex VIII allows a limited submission for mixtures intended for  
4 industrial use only (see section 3.4 on use categories). This option is presented in section 4.4.

5 Companies can also decide to submit information:

- 6 • for **single mixtures** (placed on the market with one or multiple trade names, which  
7 can be included in the same submission) or,
- 8 • if certain criteria are met, to opt for a **group submission** which brings together  
9 multiple similar mixtures (differing for certain specific component types) into one  
10 submission. Information on the group submission option and the criteria to be met are  
11 provided in section 4.5.

12 The information to be submitted includes the physical, chemical and toxicological properties of  
13 the mixture, its composition and its classification. Much of this information should be available  
14 in the SDS, however a SDS under REACH usually does not contain all the information required.  
15 Duty holders may need to complement information from other sources or consult their supplier  
16 for more specific information, especially regarding composition where practical. The specific  
17 information requirements for the different submission types (standard and limited, individual  
18 and by group) are listed in Part B of Annex VIII and detailed in the following section 5 of this  
19 Guidance document.

20 It is important to underline that the language used in the submission has to be that of the  
21 Member State where the mixture is being placed on the market, unless the Member State  
22 specifies otherwise. Some of the Member States may accept submissions in English as an  
23 alternative to their own language. A table listing Member States accepting submissions in  
24 English is available on ECHA Poison Centre website at <https://poisoncentres.echa.europa.eu/>.  
25 When the operator places the same mixture on the market in more than one Member State,  
26 the individual submissions will need to be made in all the appropriate languages.

27 The PCN portal developed by ECHA largely supports multilingualism by allowing the  
28 preparation of the submission in the preferred language as well as supporting in the  
29 distribution of the information in the language(s) of the relevant Member State(s) for example  
30 by means of a structured format containing standard phrases (see section 6.2).

31

## 32 **4.2 The UFI for mixtures and products**

### 33 **4.2.1 What is a UFI?**

34 Poison centres and appointed bodies have reported experiencing problems with the correct  
35 identification of the mixture in case of accidental exposure in up to 40 % of the calls they  
36 receive. Therefore, as part of the harmonisation of information requirements, a unique  
37 alphanumeric code to be printed on or affixed to the label of a product was introduced as an  
38 additional means of identification of a mixture. This code, or UFI (Unique Formula Identifier) is  
39 a unique 16-digit alphanumeric code that unambiguously links the submitted information on a  
40 mixture (and hence information relevant for the treatment of patients) to a specific product  
41 placed on the market. Here, we refer to a mixture as a formulation containing the chemical  
42 components having associated properties for example composition, toxicological properties,  
43 colour, and pH, while a product refers to the mixture in the form in which it is supplied to the  
44 user and defining the other aspects for example trade name, packaging, and product category  
45 (i.e. intended use).

46 All products labelled and for which submission is made with the same UFI need to share the  
47 same composition. However, different UFIs can be used for the same mixture, as long as those

1 UFI have been submitted to the appointed bodies. The same mixtures may be placed on the  
2 market under different trade names and by the same or different operators. In those cases,  
3 operators can decide to use the same UFI, as long as the mixture composition does not change  
4 or the variation is limited and does not have an impact on the toxicological information (see  
5 section 5 for details). For marketing and/or confidentiality reasons, operators may also decide  
6 to generate and affix on the label of each product a different UFI although the mixture  
7 composition of those products remains the same. In such case, all UFIs assigned to the  
8 mixture must be provided as part of the submission for that mixture.

9 The UFI is meant to complement the other means used by poison centres to identify the  
10 mixture, such as the product and/or brand name. When entering the UFI in their databases,  
11 appointed bodies or poison centres may find several products and related submissions, but all  
12 those products or submissions will have or describe the same composition (or compositions  
13 with very limited differences, see section 5.4 for details). Below an example is given of what a  
14 UFI looks like:

15  
16 **UFI: E600-30P1-S00Y-5079**  
17

18 The UFI is an information requirement to be submitted to the appointed body according to  
19 Annex VIII.

#### 20 **4.2.2 Generation of UFI**

21 Companies are responsible for the generation and management of the UFI for their mixtures. A  
22 software application (the UFI generator) has been developed to allow industry to generate  
23 UFIs. ECHA provides the tool and the user guide free of charge. Both are available on the  
24 ECHA Poison Centres website at <https://poisoncentres.echa.europa.eu/>.

25 The UFI of a specific mixture is based on the value added tax (VAT) number of a company and  
26 a formulation number assigned by the company to this specific mixture. The use of the VAT  
27 number is meant to ensure that there is no duplication between UFIs generated by two  
28 different companies. Indeed, different companies will use similar formulation numbers, but as  
29 long as they use different VAT numbers, the algorithm generates a new UFI each time. The  
30 VAT number therefore is by no means used for identification or tracking of companies or  
31 products.

32 Companies are responsible for generating and managing the UFIs under a specific VAT  
33 number. They need to communicate internally and manage properly the formulation numbers  
34 used under a specific VAT number to ensure that every mixture composition has its own UFIs –  
35 in other words, the same UFIs must never be used for mixtures that have different  
36 compositions, except for group submissions where mixtures may differ in perfume or fragrance  
37 components up to 5% (See section 4.5). A certain degree of flexibility is allowed in the use of  
38 the UFIs in order to ensure confidentiality of business information (see examples below in  
39 4.2.3).

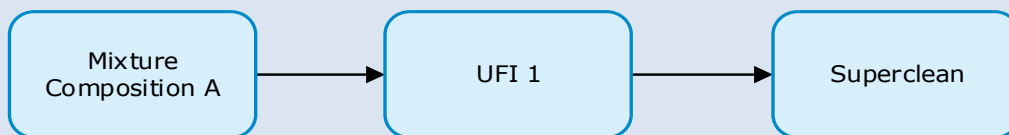
40  
41 Note that in specific circumstances there is an alternative method for companies to generate  
42 UFIs if they do not have a VAT number through the same software application (more  
43 information available in the UFI generator user guide).

#### 44 45 **4.2.3 How to use UFI**

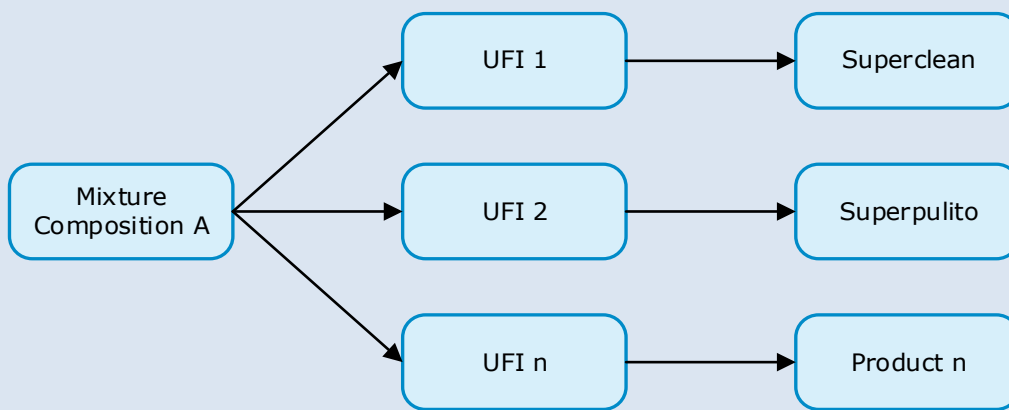
46 In this section a number of examples are presented showing with increasing level of  
47 complexity how and when a UFI has to, or can be, generated; graphical representations are  
48 also provided to support the reader. The following examples illustrate the flexibility around UFI  
49 generation and its use, while ensuring the essential condition is fulfilled: the same UFI(s) can  
50 be used for several products only if those products share the same composition according to  
51 concentration ranges defined in Annex VIII (See section 4.5).

1 Note that the same UFIs can be used across the EU market for the same mixtures, providing  
2 that for those mixtures submission including the UFIs has previously been done to the relevant  
3 Member States.

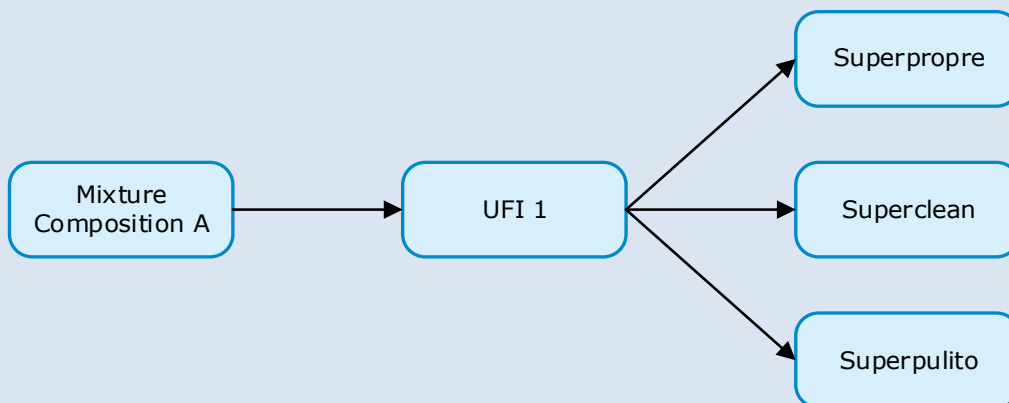
4 **Example 7:** 1 Mixture composition– 1 UFI – 1 product placed on the market ("Superclean")



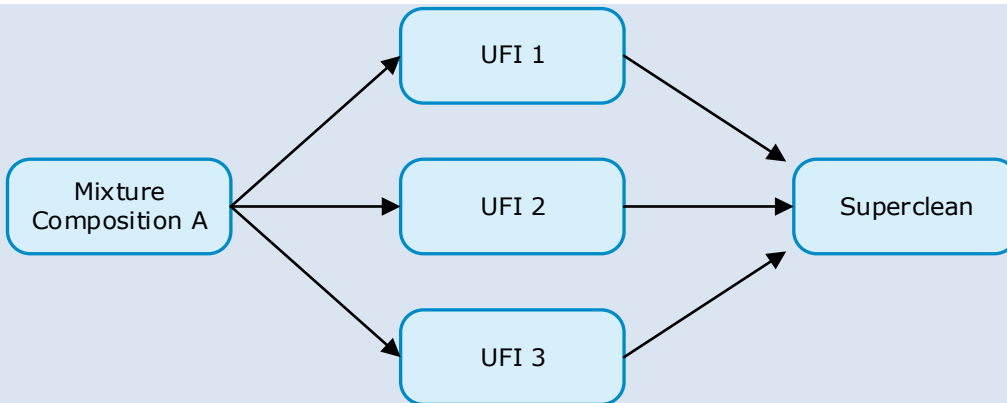
9 **Example 8:** 1 Mixture composition– 2 or more UFIs – 2 or more products placed on the market with same composition



14 **Example 9:** 1 Mixture composition – 1 UFI – 3 products placed on the market



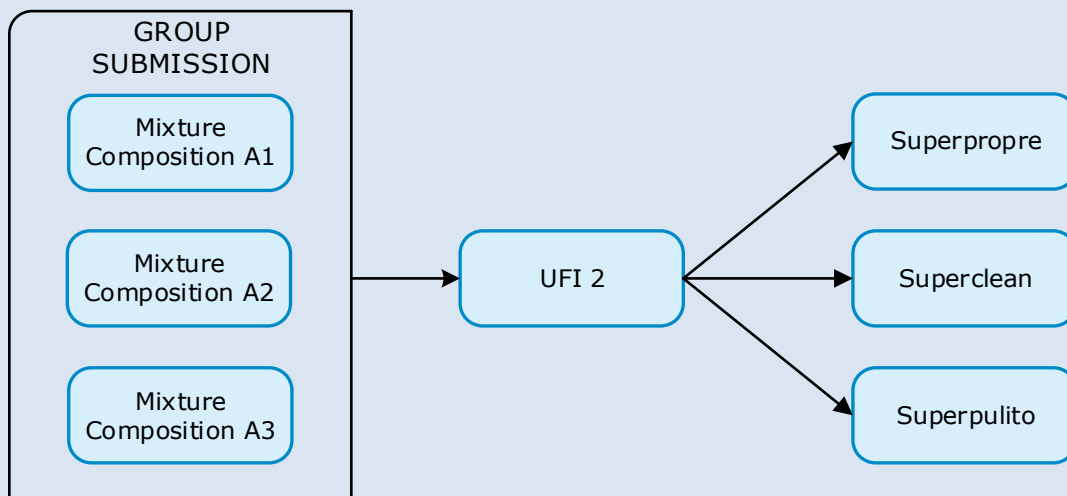
18 **Example 10:** 1 Mixture composition – 2 or more UFI – 1 product placed on the market



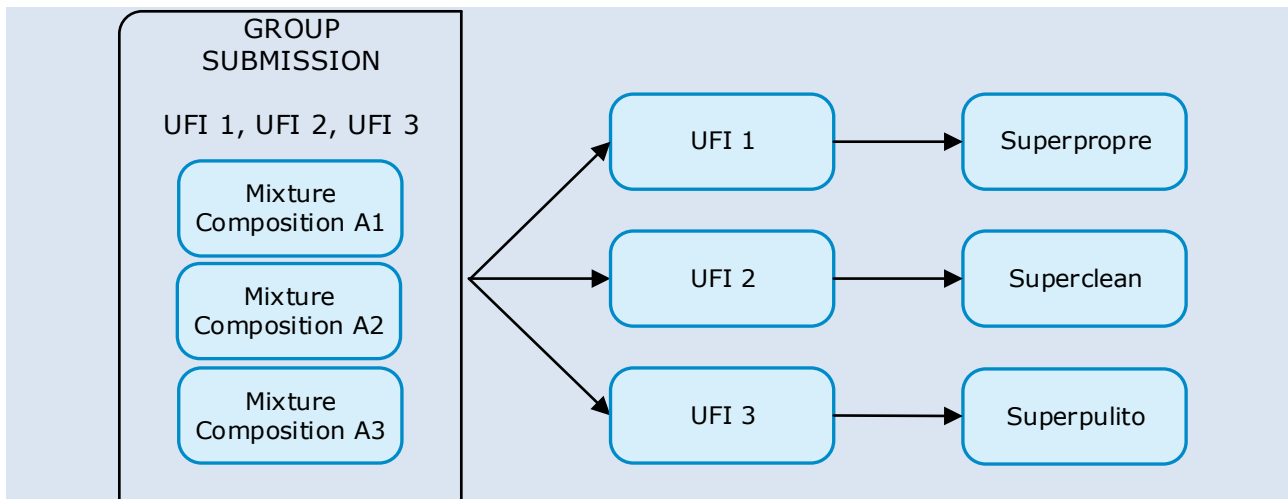
**Note to examples 8 to 10:** When several UFIs have been generated and assigned to one mixture, all those UFIs need to be included in the submission to the relevant MS and can be submitted individually or in the same submission. When more than one UFI is assigned to the same product (containing the same mixture), it is sufficient to include only one UFI on the label of the product (example 10) while all UFIs should be indicated on the SDS.

For group submissions, one UFI can be used to cover the whole group of mixtures (although it is not an obligation) even though the mixtures in a group do not necessarily have the exact same composition. This is illustrated in examples 11 and 12 below. Note that the allowed differences in the composition of mixtures in a group submission are limited (see section 4.5 and 5.4 for details).

**Example 11:** Three similar mixtures (1 Group submission) - one UFI, one or more products placed on the market



**Example 12:** Three similar mixtures (1 Group submission) – several UFIs, one or more products placed on the market.



1  
2  
3

#### 4.2.3.1 UFI and mixtures in a mixture

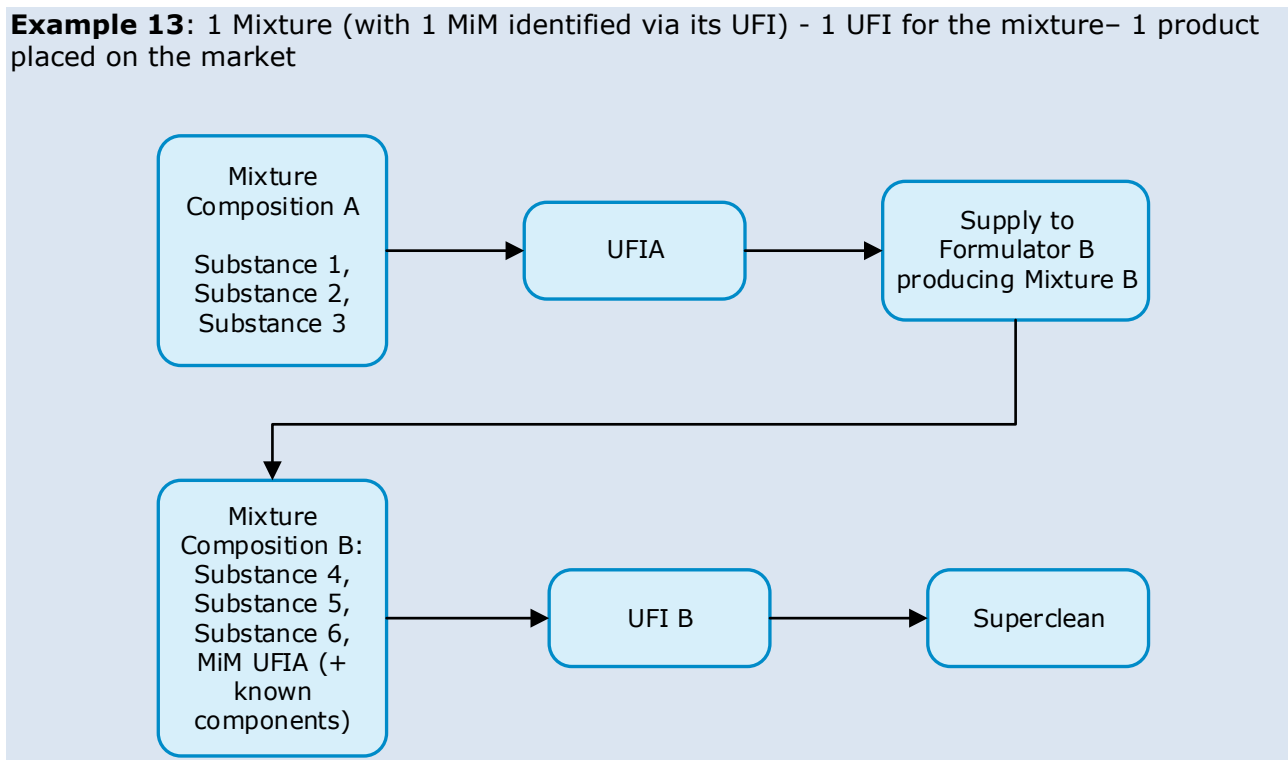
4 As defined in Annex VIII, mixture components can include other mixtures, referred to as  
5 mixtures in mixtures (MiM). By default, duty holders need to submit information on the full  
6 composition of their mixture and therefore include information on the MiM composition.  
7 However, when there is no access to the full composition of the MiM supplied, the MiM's UFI  
8 can instead be indicated in the submission together with the known MiM's components (at least  
9 those found in the SDS). Provided that the submission for the MiM has been previously made  
10 to the relevant appointed bodies, having the UFI of the MiM will allow appointed bodies (and  
11 ultimately the poison centres) to link the mixture submission with the submission of the MiM  
12 and retrieve the relevant information in case of an emergency involving the mixture containing  
13 such MiM.

14 More details about information requirements for mixtures and their components is provided in  
15 section 5.

16

17 **Example 13:** 1 Mixture (with 1 MiM identified via its UFI) - 1 UFI for the mixture- 1 product  
18 placed on the market

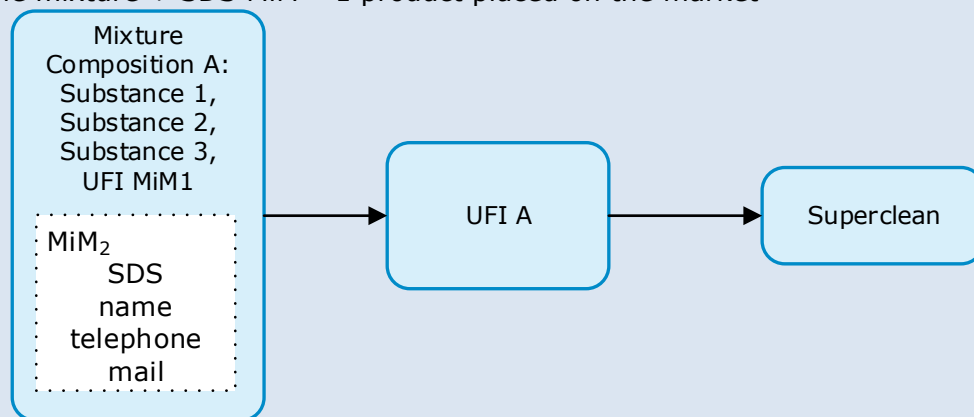
19



20

1 If the MiM does not have a UFI and the composition is not known, as a last resort the safety  
2 data sheet of the MiM must be provided as well as the name, email address and telephone  
3 number of the MiM supplier (see section 5 for more details on information requirements).

4 **Example 14:** 1 Mixture (with 2 MiMs, the first identified via its UFI, the second via its SDS) -  
5 1 UFI for the mixture + SDS MiM – 1 product placed on the market



6  
7

#### 8 4.2.3.2 Use of the UFI along supply chain and for legal entity changes

9 As long as the mixture composition remains the same, the same UFI can (but does not  
10 necessarily have to) be used by other downstream users/formulators in the supply chain (in  
11 case of a formulator, this would become the UFI of a MiM). In other words, if a downstream  
12 user purchases a product with a UFI and does not modify the mixture, they can choose to use  
13 the same UFI for their own products and in their own submission. Alternatively, the  
14 downstream user may generate and submit a new UFI.

15 There may be cases (during the transitional period) where suppliers may decide to include the  
16 UFI on the labels already before making the submission (i.e. there is no obligation to submit  
17 yet, and the UFI is printed on the label voluntarily). In these cases it is strongly recommended  
18 to clearly communicate to the downstream user (that may use that mixture as MiM) that the  
19 information on the MiM has not been submitted yet.

20 If the company generating the original UFI changes legal entity or ceases its activity, the UFI  
21 already generated remains valid and can continue to be used by the company successor, as  
22 long as the mixture composition remains the same (in the allowed concentration ranges  
23 defined in Annex VIII).

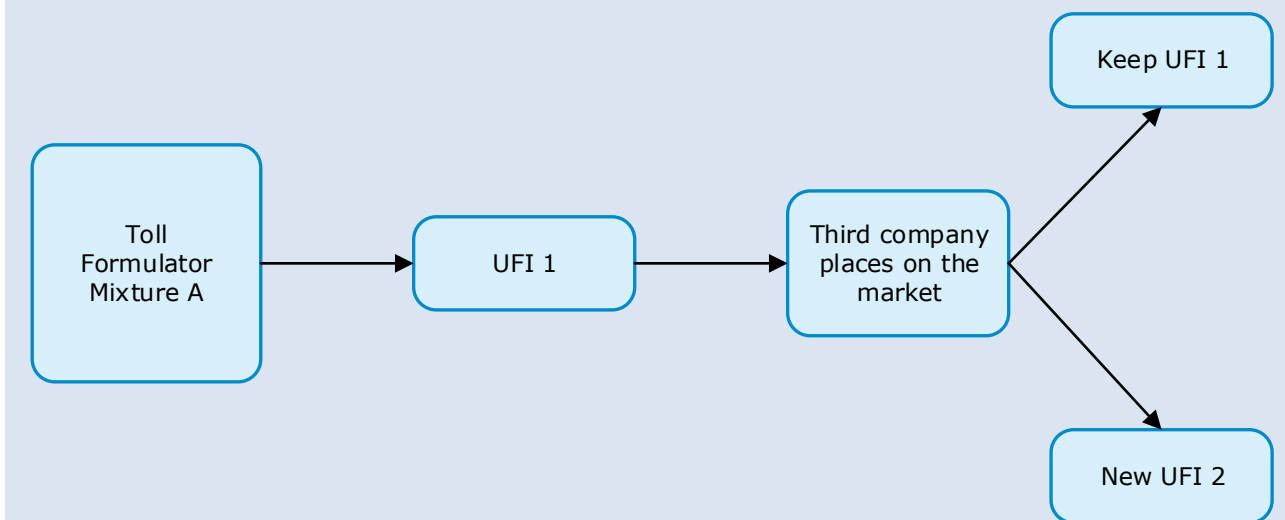
24  
25

#### 26 4.2.4 Toll formulator and UFIs

27 A toll formulator is a service providing company that formulates a mixture on behalf of another  
28 company i.e. a 'third company' and often also provides the label with the contact details and  
29 brand name of the customer (more details are in section 3.1). With regard to the use of the UFI,  
30 the toll formulator has to generate a UFI for the mixture placed on the market, include it in their  
31 submission and provide it to their customer. If the customer does not change the formulation,  
32 they can use the original UFI provided by the toll formulator. Alternatively, the toll formulator's  
33 customer can create a new UFI if desired (e.g. in case of relabelling) which needs to be included  
34 in the toll formulator's submission to the Member States where it is placed on the market (and  
35 include it on the label) – bearing in mind that the toll formulator remains the duty holder.  
36 Alternatively, it can be agreed by the two parties that the toll formulator's customer makes the  
37 submission, including their new UFI, on behalf of the toll formulator (which remains duty holder).

38

1 **Example 15:** 1 Mixture by a toll formulator - 1 UFI for the composition – a third company  
2 places on the market/rebrands – Original UFI or new UFI



3  
4

#### 5 **4.2.5 UFI and non-EU suppliers**

6 In case of import, UFI can be used in the communication with a non-EU supplier. The following  
7 ways can be considered to work around possible communication problems:  
8

9 (a) [Non-EU supplier acting on EU market via its EU-based legal entity] The non-EU supplier  
10 has a legal entity based in the EU (or a contractual agreement with an EU-based legal entity),  
11 which creates a UFI and makes a voluntary<sup>29</sup> submission to the Member States where the EU  
12 importer intends to place the mixture on the market. The non-EU supplier informs their  
13 customer (the EU-importer) about this UFI and confirms that the submission is done.  
14 Subsequently, the EU importer, who is the actual duty holder, makes their own submission  
15 with a reference to this UFI in relation to the compositional information. The importer could  
16 therefore make a submission for a mixture containing 100% of the MiM supplied by the non-EU  
17 supplier. This option could be useful also when the EU importer uses the mixture to formulate  
18 another mixture, and the non-EU supplier wants to protect the confidentiality of the  
19 information on the mixture they supply to the EU importer. The obligation to place UFI on the  
20 label lies with the importer. It is possible for the non-EU supplier to already label their product  
21 with the correct UFI before supplying it to the importer.

22 (b) [Non-EU supplier acting as a third party notifying on behalf of the duty holder] The non-EU  
23 supplier creates the UFI and makes the submission on behalf of their customer (EU importer).  
24 In this case they become a third party (see note in section 3.1). The submission will include  
25 the EU importer's details as duty holder. Depending on the agreement between duty holder  
26 and the third party, duty holder may not always be in legitimate access to data submitted on  
27 its behalf. Should the actual duty holder be restricted the access to full notification data  
28 submitted on its behalf, a contractual agreement should be established between the parties to  
29 cover the fulfilment of the obligations. Operators entering into such an agreement should be  
30 reminded about the need to exchange all the information which is necessary for the  
31 submission (e.g. end uses<sup>30</sup> and relevant Member States) and to consider the need for future  
32 updates.

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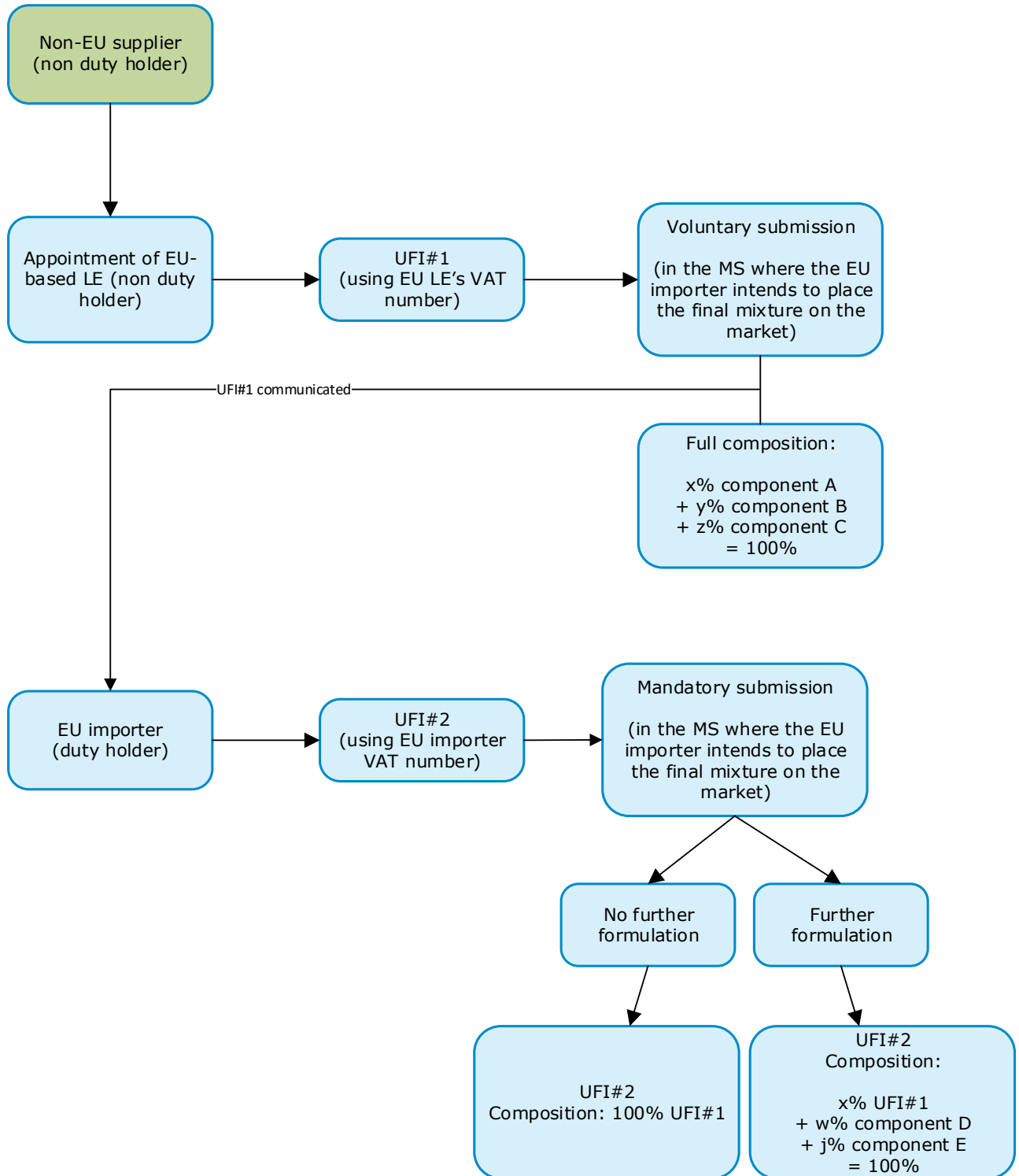
<sup>29</sup> The non-EU entity is not legally required to do so under CLP (they do not place the mixture on the EU market). More about voluntary submissions in section 3.3.1.3

<sup>30</sup> Details on end use concept is provided in section 3.4.



1 In both cases, the EU importer and non-EU supplier are strongly recommended to enter into a  
 2 contractual agreement to cover the details of the submission approach chosen. It should be  
 3 kept in mind that that the EU company remains in any case the duty holder and therefore  
 4 responsible in front of the enforcement authorities.

5 **Example 16:** Import into the EU – Non EU supplier acting via EU-based legal entity to protect  
 6 CBI



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#### 4.2.6 How to manage UFIs

Companies will need to keep an overview in their internal systems of which mixture corresponds to which UFI and keep track of changes and updates (the main reasons being to avoid the use of the same UFI for mixtures with different compositions).

It is strongly recommended that the data management system allows maintaining and recording for internal use the relation between the following values for every mixture:

- The UFI;
- The VAT number used to generate the UFI
- The internal formulation number used to generate the UFI;
- The internal formulation code of this mixture, if different from the formulation number.

As described in the user guide on “UFI generator application”<sup>31</sup> the UFI is generated on the basis of a company VAT number and on an internal formulation number. The latter needs to be a 9-digit number between 0 and 268435455 and therefore companies need to keep their own records/cross referencing and manage an internal mapping of their formulation codes with the internal formulation numbers.

Normally companies identify their products with an internal code; it is highly unlikely that such internal codes can be used directly for the generation of the UFIs since the former often contain letters, special characters or more than 9 digits. Therefore, if the company's internal coding system cannot be adapted to be used directly in the UFI tool, it is necessary to convert the original internal code and generate a new internal company formulation number based on which a UFI can be created.

In addition, if a single existing internal company code is used to represent different mixtures, it could be necessary to generate new different internal codes for each mixture to be used in the UFI generation. This may be necessary in order to ensure different UFIs are assigned to mixtures with differences in composition (this is likely to be the case when mixture management or SDS generation tools are used by the company).

It is strongly advised to record the information mentioned above. Mapping should be established in the system that companies/submitters will use to manage their submissions in order to guarantee that a correct relation is maintained between the mixture information stored (company, trade name, composition, physico-chemical properties, classification) and its UFI. This will be useful for the efficient management of the current products (e.g. different batches of the same mixture for which labels have to be created) and to keep track in case of updates.

#### 4.2.7 New UFI as a result of composition changes

Since the main purpose of the UFI is to unambiguously link a product on the market and the corresponding information relevant for an emergency health response, the UFI is always linked to a specific composition<sup>32</sup>. Annex VIII to CLP requires that a new UFI be created in case the

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<sup>31</sup> Available at <https://poisoncentres.echa.europa.eu/ufi-generator>.

<sup>32</sup> Note, in case of group submission the same UFI could be used to refer to several similar mixture compositions.

1 mixture composition changes according to certain criteria. In particular, a new UFI has to be  
2 created when there is:

- 3 **1. A change of components (addition, substitution or deletion of one or more**  
4 **components)** - the addition, substitution or deletion of one or more components is  
5 considered a major change requiring the creation of a new UFI<sup>33</sup>. Note that this applies  
6 to the components which are required to be indicated in the submission (e.g. the  
7 change in a component which is not classified for health or physical effects and present  
8 in concentration < 1% would not require a new UFI). A derogation to this principle is  
9 provided for mixtures in a group submission containing perfumes or fragrances if the  
10 change in the composition only relates to those components. To be noted that if a  
11 fragrance or perfume component is removed from all the mixtures of the group an  
12 update of the submission is required (see section 7.4.6; according to B.3.1 perfume or  
13 fragrance components have to be present in at least one mixture of the group).
- 14 **2. A change in concentration beyond the concentration range provided in the**  
15 **original submission** – For the declaration of the concentration of mixture components  
16 it is possible to use concentration ranges (see section 5.3 on information on mixture  
17 components). If the new concentration of a particular component exceeds the given  
18 range (indicated in the original submission) a new UFI has to be created and an update  
19 of the submission has to be provided accordingly. If the change is within the range,  
20 there is no requirement to update the UFI and no requirement to update the  
21 notification.
- 22 **3. A change in concentration beyond the limits allowed for exactly declared**  
23 **concentrations** - For the declaration of the concentration of mixture components it is  
24 possible to use the exact concentration, in which case concentration changes are  
25 allowed within certain limits. If the new concentration exceeds the allowed variation, a  
26 new UFI has to be created and therefore an update of the submission has to be  
27 provided accordingly. If the new concentration does not exceed the allowed variation,  
28 (which is always measured against the initial submission, regardless of the number of  
29 possible subsequent voluntary updates), the submission can be voluntarily updated  
30 without the need for a new UFI. The same applies in case of further changes as long as  
31 the new concentration does not exceed the total allowed variation.

32 It should be noted that the changes discussed in this section concern components which are  
33 required to be indicated in the original submission, so besides triggering the need to create a  
34 new UFI these changes trigger at the same time the need to update the whole submission.  
35 More details are provided in section 7.4.

36 The UFI should be updated also when the indicated range of one or more components are  
37 changed, even if the actual concentration remains the same. For example a concentration of  
38 30% of a particular component is originally indicated with the range 28-33% and the submitter  
39 changes the indicated range to 30-35% (without changing the actual concentration). Since  
40 poison centres normally use the upper range limit in their assessment (calculation of  
41 exposure), the same UFI for two different submitted compositions may generate confusion.

42 It is also to be noted that changes to the UFI may occur as a result of a commercial decision of  
43 the company, even if none of the above conditions are fulfilled (the composition remains the  
44 same and a change of the UFI is not legally required). A company may decide to change the  
45 UFI voluntarily whenever other changes occur, possibly because of their internal change  
46 management system (an example would be a change of packaging which is considered by the  
47 company as a new product). For voluntary changes of UFI, an update of the submission is

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<sup>33</sup> To be noted that the substitution of one component with another with identical composition and hazard profile (possibly following a change of supplier) does not trigger the need for an update or a new submission.

1 required the same way as for the mandatory change of UFI.

#### 2 4.2.7.1 Changes in MiM's UFI

3 When a mixture is used by an operator downstream as component of another mixture, a  
4 change in the UFI of this MiM may trigger the need to update the UFI of the final mixture.

5 It may be in some cases that a MiM supplier changes the UFI either for commercial reasons  
6 (i.e. they can guarantee that the mixture composition remains the same), or the mixture  
7 composition has changed. In both cases the submission for the MiM needs to be updated to  
8 add the new UFI.

9 Where the MiM composition has changed, the new MiM UFI will also need to be reflected in the  
10 submission of information for the final mixture (see the examples in section 7.4.4) and this  
11 requires also the UFI of the final mixture to be changed.

12 If the UFI of the MiM changes for commercial reason only (i.e. no changes in the composition)  
13 there is no impact on the final UFI and therefore it does not need to be changed. The  
14 submission will need to be updated by adding the new MiM's UFI (more information on update  
15 rules are provided in section 7.4).

16

#### 17 4.2.8 Display, position and placement of UFI

18 The UFI must be printed on or affixed to the label of the hazardous mixture for which  
19 submission obligations apply<sup>34</sup> (see derogations mentioned in section 4.2.7.2).

20 The UFI, since it is part of the label, also needs to be reflected in Section 2.2 of the SDS<sup>35</sup>. In  
21 cases where the UFI is not included on the label (e.g. mixtures for industrial use or mixtures  
22 not packaged, see section 4.2.7.2 below), it is sufficient to include it in Section 15 of the SDS.

23 The UFI code itself must be preceded by the acronym "UFI" in capital letters and must be  
24 clearly visible, legible and indelibly marked. The acronym "UFI" must always be used using  
25 the Latin alphabet, independent of the country, language and national alphabet(s).

26 The legal text specifies that the UFI must be indicated on the label but it does not cover other  
27 requirements that should be taken into account when preparing the label information. The  
28 following suggestions are provided to enhance the recognition of the UFI by users and  
29 consumers and to assist the communication with appointed bodies and poison centres.

30

31 • No additional marker than "UFI" should appear before the actual UFI code.

32 • Affixing the UFI to the label is possible instead of printing directly on the label. It is  
33 recommended that the sticker is affixed firmly so that it cannot easily be separated  
34 from the actual label. Affixing the UFI may seem to be a useful option in the following  
35 cases:

36 ○ To avoid wasting labels printed before the applicability of Annex VIII and where  
37 still valid (though without UFI printed);

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<sup>34</sup> Note, the possibility to alternatively print the UFI on the packaging has been discussed with the PEG and CARACAL 27th. It was agreed to assess the option and decide whether it requires a possible amendment of the legal text or simply revise the interpretation in the Guidance. Furthermore, the requirements for including the UFI in the SDS may be revised via a possible amendment of Annex II to REACH. The Guidance may be therefore revised accordingly after a decision is taken and the possible relevant amendment of the relevant legal text.

<sup>35</sup> Section 2.2 of Annex II to REACH. See also ECHA *Guidance on the compilation of SDSs*.

- To mitigate the need of frequent changes to the label, in case the product changes the composition dynamically (e.g. seasonal changes or frequent changes of suppliers).

- To help distinguish the acronym from the beginning of the UFI, a colon ":" can be used to separate the "UFI" acronym from the UFI code. An optional space may be placed after the colon (e.g. if it can improve the legibility using the selected font).

The three hyphens separating the blocks of the UFI must be printed. Alternatively, the UFI can be printed on two lines and the second hyphen omitted. In the latter case, using a monospaced font is strongly advised to keep the blocks aligned.

This leads to strings such as

**UFI:VDU1-414F-1003-1862**  
(23 characters)

**UFI: VDU1-414F-1003-1862**  
(24 characters)

**UFI: VDU1-414F**  
**1003-1862**  
(23 characters on two lines)

Font colour also needs to be considered. For example, black on a light background is a good option; conversely, a light coloured font should be used on a dark background. In principle, any colour can be used, notably in order to consider the printing equipment capabilities, provided it meets the requirements of being clearly and indelibly marked.

Monospaced style fonts have proven to be suitable - especially when printing the UFI on two lines, as shown above, as they tend to improve the legibility of individual characters. The size of the font is recommended to be adapted to the font style to ensure that the UFI is legible for a person with average eyesight (e.g. legibility could be improved by using a slightly larger font size for a bolder font; more details can be found in section 5.2 of the *Guidance on Labelling and Packaging in accordance with CLP*<sup>36</sup>).

There are no clear rules concerning the positioning of the UFI on the label. Article 25(7)<sup>37</sup> of CLP further defines the UFI as (obligatory) supplemental information and this type of information in general, should be located in the section for 'supplemental information' on the label' for example near the hazard pictograms (see section 4.8 of *Guidance on Labelling and Packaging in accordance with CLP*). Moreover, as outlined in Annex VIII (part B 1.1), the UFI is a product identifier of the mixture, together with the trade name or other variant names and therefore, in order to improve visibility and facilitate the user in the identification of the product, could be placed (with the "UFI" marker) in proximity of the product name or trade name. In any case, where the UFI is positioned is left to the discretion of the person responsible for compiling the label, though as a general rule, the information should be structured in a way that is easy to read and understand.

<sup>36</sup> See *Guidance on Labelling and Packaging in accordance with Regulation (EC) 1272/2008* at <https://echa.europa.eu/guidance-documents/guidance-on-clp>

<sup>37</sup> Regulation (EU) 2017/542 amended CLP by adding the new Annex VIII and the additional paragraph 7 to Article 25 (Additional labelling information).

1 In general the placement of the UFI, for example on inner and outer packaging, will follow the  
2 general rules in accordance with Article 33 of CLP. The UFI is considered to be part of the  
3 supplemental labelling information (even if it is at the same time an additional product  
4 identification element) and the corresponding labelling requirements need to be followed. The  
5 *Guidance on Labelling and Packaging in accordance with CLP*, provides, in particular but is not  
6 limited to, information on:

- 7
- 8 • Exemptions for labelling requirements in specific cases in section 5.3 (e.g. small  
9 packaging, use of fold-out labels and outer packaging).
- 10 • Specific rules for transport labels and labelling outer, inner and single packaging in  
11 section 5.4.
- 12 • Example labels e.g. for multi-component products in section 6.

#### 13 14 4.2.8.1 Multi-component products

15 Mixtures can be placed on the market not only as products containing a single mixture, but  
16 also as part of a set of multiple mixtures (e.g. reagent or testing kits). In these cases, each  
17 single mixture bears the label relevant to that mixture, where required<sup>38</sup>. Each mixture that is  
18 part of a set and is classified as hazardous regarding human health or physico-chemical  
19 properties, has to have its own UFI, which needs to be included on the respective label.

20 In some cases, mixtures are placed on the market as parts of a multi-component product,  
21 where each mixture is in a separate container, but the containers are purchased together and  
22 a new mixture is created upon the use of the product (e.g. certain adhesives). The company  
23 placing multi-component products on the market must provide a UFI for each component-  
24 mixture in separate submissions<sup>39</sup>. Nevertheless information concerning the final mixture is  
25 also potentially important for the emergency response, and should be provided (if available  
26 and relevant) in the submission of the component mixtures (e.g. in the toxicological section).  
27 The proportion in which the component mixtures are foreseen to be mixed in the final mixture  
28 is an example of such final mixture related information which could be provided. Section 6.2 of  
29 the *Guidance on Labelling and Packaging in accordance with CLP* provides relevant additional  
30 information and examples on the labelling of these specific products.

#### 31 32 4.2.8.2 Exemption from labelling requirements [A.5.3]

33 For mixtures which are intended for industrial use it is not mandatory to include the UFI on the  
34 label provided it is indicated in the SDS. In this case the UFI should be included in Section 15  
35 of the SDS (not Section 2.2 since it is not included in the label). This includes industrial  
36 mixtures that are further formulated into 'final mixtures' for consumer or professional use i.e.  
37 the derogation applies even if the condition for a limited submission are not met. The same  
38 derogation applies for mixtures irrespective of the end user type which are placed on the  
39 market but not packaged (e.g. cement).

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<sup>38</sup> See *Guidance on Labelling and Packaging in accordance with Regulation (EC) 1272/2008* at  
<https://echa.europa.eu/guidance-documents/guidance-on-clp>

<sup>39</sup> The rationale is that the obligation to submit information concerns mixtures actually placed on the market, i.e. the single mixtures which are part of the product, and not the mixture created upon use. Furthermore, the label of the product bears the information on the component mixtures (and hence their UFIs) and not of the final mixture.

### 1 **4.3 EuPCS**

2 A harmonised European product categorisation system (EuPCS) maintained by ECHA<sup>40</sup> is used  
3 to describe the intended use of a mixture for which information according to Annex VIII has to  
4 be submitted (section 3.4 of part A of Annex VIII). Examples of product categories from  
5 version 1 of the EuPCS include "Hand dishwashing detergents", "Adhesives and sealants for  
6 construction", "Decorative paints and coatings"<sup>41</sup>. The product category does not cover  
7 toxicological information, composition or type of packaging, which should be provided in other  
8 sections of the submission format.

9 Information on a mixture's product category may be used to support poison centres and  
10 appointed bodies in a harmonised approach to statistical analyses and reporting of poisoning  
11 cases between EU Member States. In addition, the EuPCS may serve as an additional aid to  
12 poison centres in the identification of the product in a poisoning case where no other  
13 information for identification is available.

14 When making a submission for a hazardous mixture, duty holders must assign a product  
15 category which best defines the intended use of the product(s). The same principle is followed  
16 in the case of mixtures that may fit multiple product categories, for example, a 2-in-1 laundry  
17 detergent also containing a stain removal agent: it is the responsibility of the notifier to select  
18 the main intended use, which in this case, the main intended use would likely be a laundry  
19 detergent. In the specific case where a mixture has a dual use, one of which has either a  
20 biocidal use or a plant protection product use (e.g. a detergent that is also a biocide), the main  
21 intended use must always be categorised according to the corresponding biocidal or plant  
22 protection product category.

23 It should be noted that the main intended use referred to in this section is different from the  
24 intended use types, i.e. a mixture for consumer uses, professional uses or industrial uses, as  
25 described in section 3.4. The 'use type' is based on the final end user of the mixture (and  
26 determines the information requirements) while the 'main intended use' is based on the user  
27 next in the supply chain. To illustrate this, consider an 'original mixture' for example raw  
28 material fragrance mixture, which is eventually incorporated into a 'final mixture' for example  
29 a detergent that is subsequently placed on the consumer market. As the raw material has a  
30 consumer end use, the submission will need to be made fulfilling the information requirements  
31 for mixtures for consumer use (i.e. deadline for submission 2020) and its intended use must  
32 be categorised as code 'F' - 'Mixtures for further formulation'.

33 The EuPCS has been published on the ECHA Poison Centres website along with a practical  
34 manual to support categorising products according to their intended use.

35  
36 ECHA is responsible for the maintenance and any changes to the EuPCS. Requests for updates  
37 or adaptations can be made by accredited stakeholders following the procedure detailed on the  
38 ECHA Poison Centre website.

### 39 **4.4 Limited submission**

40 The importers and downstream users of hazardous mixtures placed on the market for

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<sup>40</sup> The current EuPCS is based on the system originally developed by the Commission following the "Study on a Product Category System for information to be submitted to poison centres" available at <http://ec.europa.eu/growth/sectors/chemicals/poison-centres/>.

<sup>41</sup> [EuPCS](#) is available from the ECHA Poison Centre website.

1 industrial use only, have the possibility to opt for a 'limited submission' as an alternative to the  
2 general submission requirements [A.2.3].

3 In such cases, information on the composition of their industrial mixtures submitted to the  
4 appointed body may be limited to the information contained in the safety data sheet ('SDS').  
5 However, it must be ensured that additional detailed information on the composition of such  
6 mixtures is rapidly available on request, in the event of an emergency health incident [A.2.3  
7 and B.3.1.1]. The rationale for this specific regime is provided in Recital 11 of Regulation (EU)  
8 2017/542,<sup>42</sup> which specifies that "*on industrial sites there usually is a greater knowledge of the*  
9 *mixtures used and medical treatment is generally available. Therefore, importers and*  
10 *downstream users of mixtures for industrial use should be allowed to fulfil limited information*  
11 *requirements.*" The regulatory burden for the industry is thus tailored proportionally upon the  
12 specific needs of the 'industrial use'.

13 Companies which intend to make a limited submission are invited to consult *ECHA's Guidance*  
14 *on the compilation of safety data sheets*,<sup>43</sup> providing comprehensive guidance on the  
15 compilation and handling of SDSs.

16 Typically, an SDS is less detailed than what is required in a 'full submission' pursuant to Annex  
17 VIII to the CLP. See section 5.3.4 for more information.

18  
19 It needs to be noted that if a submission was made for a mixture originally intended for  
20 industrial use only (limited submission) and this mixture starts being used in consumer or  
21 professional products, the full set of information required for a standard submission needs to  
22 be submitted before placing on the market the products with the new use type.

#### 23 24 25 **4.4.1 Contacts for rapid access to 'additional detailed product information'**

26 The submitters who have chosen the 'limited submission' must, according to section 2.3 of Part  
27 A and section 1.3 of Part B of Annex VIII, provide in the submission the contact's details for  
28 rapid access to 'additional detailed product information'.

29 These contact details must include as a minimum:

- 30 • the name of the submitter, responsible for the placing on the market of the hazardous  
31 industrial mixture;
- 32 • a telephone number accessible 24 hours per day and 7 days per week, where 'additional  
33 detailed product information', which is not included in the SDS but would be requested  
34 by Annex VIII in a standard submission, can be obtained by the appointed body in case  
35 of an emergency;
- 36 • an email address for follow-up exchange of information between the submitter and the  
37 responsible authority or medical personnel.

38  
39 Please note that the contact details could belong to the submitter or to a third party appointed  
40 under the responsibility of the submitter in charge to deliver the required information.

41 The person who is requested to provide the additional information may want to verify that the  
42 request comes from an appointed body. As an example, a reference to a submission identifier<sup>44</sup>  
43 could serve this purpose as it should be available to the submitter and authorities only.

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<sup>42</sup> [Commission Regulation \(EU\) 2017/542](#) of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response

<sup>43</sup> *Guidance on the compilation of safety data sheets*, in particular section 3.3 'Composition/ information on ingredients'.

<sup>44</sup> At the time of drafting of this guidance the exact form of such an identifier was still to be determined at technical level.



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#### 4.4.2 Availability and content of the additional information and rapid access

3 The 'additional detailed product information' within the meaning of Annex VIII must be such to  
4 allow a responsible authority or medical personnel dealing with a poisoning/ health incident, to  
5 formulate adequate preventative and curative measures. The information on the composition  
6 required for a 'full submission' pursuant to section 3.4 of part B of Annex VIII, is considered  
7 sufficient for this purpose. It must be kept readily accessible to be supplied on request to the  
8 responsible authority or medical personnel dealing with a poisoning/ health incident.

9 As it is not possible to safely define "rapid" access, the information is expected to be provided  
10 without delay.

11 Note that rapid access must be provided in a language(s) of a Member State where the  
12 mixture is placed on the market. Additionally, the telephone number should not generate  
13 disproportionate cost to the Member State (e.g. 'premium' phone numbers or numbers located  
14 outside of the EU).

15 Pursuant to Article 45.2 of the CLP the requested information can be used to meet a medical  
16 demand by formulating preventative and curative measures in the event of an emergency.  
17 Annex VIII (section B.1.3) indicates that rapid access to detailed information, in case of limited  
18 submission, has to be available for appointed bodies. It is to be underlined that it is normally  
19 poison centres (or bodies other than the appointed bodies) who are dealing with poisoning  
20 accidents and will need rapid access to the information.

21 If, following receipt of the 'additional detailed product information', the appointed body makes  
22 a 'reasoned request' according to Section 3.2 of Part A of Annex VIII to the submitter that  
23 further additional information or clarification is necessary, the submitter must provide the  
24 necessary information or clarification requested without undue delay (see section 7.2 for more  
25 details).

26 It should be noted that the 'limited submission' is optional. Operators dealing with hazardous  
27 mixtures for industrial use and who are required to make the submission, can also decide to  
28 comply with the general (full) submission requirements, thus being exempted from the  
29 obligation to provide 24/7 contact details for additional information.

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#### 4.5 Group submission

32 Companies may sometimes have in their product portfolio, a high number of similar mixtures,  
33 which may only slightly differ in certain elements. Therefore Annex VIII allows to submit,  
34 under certain conditions, information for several mixtures with a single submission, which is  
35 called 'group submission'.

36 A group submission is possible if:

37

- 38 • all mixtures in the group contain the same composition except for certain perfumes  
39 and/or fragrances under specific condition, and for each of the components, the  
40 reported concentration or concentration range is the same;
- 41 • all mixtures in the group have the same classification for health and physical hazards;  
42 and
- 43 • all mixtures in the group belong to the same product category.

44 Section 5.4 provides more details on the information required for a group submission.  
45

## 5. Information contained in the submission

The company that is placing a hazardous mixture on the market for which they have made a submission under Article 45 (as clarified in section 3), is required to submit the information specified in Part B of Annex VIII to CLP.

This section provides guidance on which information is needed according to the legal text in the case of a full submission as well as in the case of limited (see section 4.4) and group (see section 4.5) submissions. The reference to the relevant section of the legal text is indicated in brackets next each heading.

### 5.1 Identification of mixture and submitter [Part B.1]

#### 5.1.1 Product identification [B.1.1]

Poison centre operators must receive information to enable them to rapidly and accurately identify the responsible product in the event of a poisoning incident. Following a poisoning accident, this information is normally provided by the person making the call, who ideally should have the relevant product identifiers at hand on the label of the product itself. The product identifiers needed for the purposes of Article 45 and the poison centre work are laid out in Annex VIII to CLP in accordance with Article 18(3)(a) of the same Regulation. The Unique Formula Identifier (UFI) code is one of the main product identifiers on the label (as already mentioned in the previous sections) that a caller should relay to the poison centre operators to allow the identification of the poisoning agent (see section 4.2).

In addition to this, there are other elements from the label which are important to poison centre operators such as the "*complete trade name or names of the mixture [...], including, where relevant, brand name, name of the product and variant names as they appear on the label*" [B.1.1]. The same mixture could be placed on the market under several trade names and for different intended uses. As long as the composition doesn't change, all these trade names can be included in the same submission<sup>45</sup>. The provision of all the exact names in the submission as they appear on the label is necessary for the poison centres as there are cases where different products exist with the same main name (e.g. brand name or trade name) and different other names. The latter would therefore facilitate a correct identification.

#### 5.1.2 Submitter details [B.1.2]

The responsibility for submitting information on hazardous mixtures in the context of CLP Article 45 and Annex VIII is considered to be that of the duty holder who is referred to as the "submitter" (see section 3.1). Annex VIII requires that the details of the submitter, such as their name, full address, telephone number and email address are to be provided in the submission and must be consistent with those on the label of the product (as indicated in Article 17(1)(a) CLP).

A distinction must be made between the submitter, who bears the legal obligation to provide the necessary information in a submission in a consistent manner with the product label, and another natural person acting as a third party or representative of the submitter, but who may physically prepare and make the submission (see section 3.1).

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<sup>45</sup> Note that a limited variability in composition may still exist if generic product identifiers are used to cover different components. See following subsections for more details.

### 1 **5.1.3 Details for rapid access to additional product information [B.1.3]**

2 Submissions made for industrial mixtures which qualify for reduced information requirements,  
3 i.e. a limited submission, require additional contact elements for the purpose of providing an  
4 emergency responder with more information if required in case of emergency. In order to  
5 provide rapid access to this information, the submission must contain a telephone number and  
6 email address and be accessible 24 hours a day, seven days a week. This service must be  
7 provided in the national language(s) of the Member State(s) where the product is placed on  
8 the market (see section 4.4).

## 9 **5.2 Hazard identification and additional information [Part B.2]**

### 10 **5.2.1 Classification of the mixture and label elements [B.2.1 and B.2.2]**

11 The classification of the mixture for health and physical hazards has to be provided in the  
12 submission. There is no requirement for providing information regarding the possible  
13 classification of the mixture as hazardous to the environment. Environmental hazards are not  
14 related to the information needed for an emergency health response.

15 The classification for health and physical hazards needs to indicate the hazard classes and  
16 associated hazard categories relevant for the mixture (e.g. "Acute Tox. 4", "Flam. Liq. 2").

17 The labelling elements associated with the classification for health and physical hazards  
18 according to the rules set in Annex I to CLP must be provided. This includes the hazard  
19 pictogram code (e.g. GHS07), the signal word (Danger/Warning), the hazard statement codes  
20 (including supplemental hazard information) (e.g. H302) and precautionary statement codes  
21 (e.g. P264).

22 Information about the mixture classification and the associated labelling elements has to be  
23 consistent with the information provided in Sections 2.1 and 2.2 of the safety data sheet (SDS)  
24 of the mixture as specified in Annex II to REACH apart from the classification regarding the  
25 environment hazards. Note that even in situations where Annex I to CLP allows for reduced  
26 label elements, the full set of label elements indicated in Section B.2.2 of Annex VIII (and  
27 reported above) have to be included in the submission.

### 28 **5.2.2 Toxicological information [B.2.3]**

29 Annex VIII part B, section 2.3, specifies that the submission has to include the information on  
30 the toxicological effects of the mixture or its components that is required in Section 11 of the  
31 SDS of the mixture. The information requirements for an SDS are specified in Annex II to the  
32 REACH Regulation. The information to be included in the submission thus has to include as a  
33 minimum all the relevant and available information on the toxicological health effects related  
34 to each of the health hazard classes covered by Annex I to CLP:

- 35 (a) acute toxicity;
  - 36 (b) skin corrosion/irritation;
  - 37 (c) serious eye damage/irritation;
  - 38 (d) respiratory or skin sensitisation;
  - 39 (e) germ cell mutagenicity;
  - 40 (f) carcinogenicity;
  - 41 (g) reproductive toxicity;
  - 42 (h) STOT-single exposure;
  - 43 (i) STOT-repeated exposure;
  - 44 (j) aspiration hazard
- 45

46 For each of the above hazard classes the submission should include the information from  
47 Section 11 of the SDS, which will allow the poison centres to provide adequate advice in case

1 of exposure to the mixture. This could include, when available, the result of the test, reference  
2 to the species and test method used, and possibly information on the exposure period.

3 Examples are illustrated below:

- 4 - Acute toxicity, oral: LD50 1310 mg/kg (rat)
- 5 - Skin corrosion/irritation: Corrosive (rabbit, OECD 404, 20h)
- 6 - Skin sensitisation: Not sensitising (guinea pig, OECD 406)

7 Annex VIII does not prescribe any specific structure for reporting such information.  
8 Considering that it is not possible to define in general terms what information is needed for the  
9 purposes of this Annex, the full content of Section 11 of the SDS could be considered  
10 potentially relevant for the poison centres and emergency responders. The full content of  
11 Section 11 of the SDS may, for example contain information on toxicokinetics, metabolism and  
12 distribution as well as more elaborate information on the toxicological effects and test  
13 methods.

14 The submitter has to make sure that the required toxicological information is provided, in order  
15 for the poison centre to have access to the relevant information. Information included in the  
16 submission should not contain cross-references to other sections of the SDS.

17 This information should be integrated, if needed, with relevant information concerning the final  
18 mixture generated upon use in case of multi-constituent products (see section 4.2.7.1).

19

### 20 **5.2.3 Additional information [B.2.4]**

21 Additional information about the packaging, physical appearance, pH, intended use and user  
22 types of the mixture has to be provided in the submission. Some of the information below is  
23 normally contained in Section 9 of the SDS of the mixture, as specified in Annex II to REACH.  
24 In some cases, the submission covers multiple trade names under which the mixture is placed  
25 on the market (which may differ for various product's characteristics). Some of the information  
26 may need to be adequately linked to the specific trade name/product to ensure that the  
27 emergency responders can properly identify the risks.

28 The additional information is specified in Part B, Section 2.4, and includes the following:

- 29 - *The type(s) and size(s) of the packaging used to place the mixture on the market for*  
30 *consumer or professional use.* The type relates to the form of the packaging as  
31 supplied, for example a bottle, a box, a tube, a dispenser etc. The type does not relate  
32 to the nature/composition of the packaging material. The size has to be given as the  
33 nominal volume(s) or weight(s) of the packaging(s). If a mixture is supplied in different  
34 types and sizes of packaging in any given Member State, information of all the relevant  
35 types and sizes placed on the market in that Member State has to be contained in the  
36 submission. Information about the specific type of packaging linked to each trade name  
37 is useful information, for both a emergency response and statistical analysis purposes.
- 38 - *The colour(s) and the physical state(s) of the mixture, as supplied.* This information  
39 relates to the general appearance of the mixture (see section 9 of the SDS). In case the  
40 submission covers a mixture where the colouring agent(s) relevant to a specific trade  
41 name varies <sup>46</sup>, it is not necessary to indicate the specific colour of each trade name but  
42 basic generic colour names can be used. It is important that colour information is

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<sup>46</sup> For a standard submission this is possible only if the colouring agents meet specific criteria which allow use of the same generic identifier, see section 5.3 for more details on information on mixture's components.

- 1 provided taking into account its purpose, i.e. for an emergency health response and  
2 under the consideration that this information may be provided by a caller to the poison  
3 centre operator who needs to identify the mixture. The PCN provided by the Agency  
4 supports the identification of colours by providing the list of colours identified as  
5 appropriate in this context (including the possibility of indicating multiple colours as well  
6 as colourless mixtures).
- 7 - *The pH, where applicable.* (See section 9 of the SDS).
- 8 - *Product categorisation.* The product category according to the EuPCS describing the  
9 intended use of a mixture must be provided. In case the same mixture is placed on the  
10 market under different trade names with different intended uses, an appropriate  
11 product category can be allocated to each of them. Support for selecting the most  
12 suitable product category can be found in the EuPCS practical manual available on the  
13 ECHA website <https://poisoncentres.echa.europa.eu/tools>. See also section 4.3 in this  
14 document on the EuPCS.
- 15 - *Use types (consumer, professional, industrial).* The relevant use type(s) of the mixture  
16 as supplied by the submitter has to be indicated in the submission. As use type is based  
17 on end-use, the end-user group must also be reflected since the final end-use of the  
18 mixtures determines the deadline for submission and information requirements. For  
19 example in case the mixture is supplied for professional use but is also available for  
20 consumer use, then consumer use has to be reflected in the submission. Similarly, the  
21 submission concerning a mixture for industrial use needs to additionally reflect the  
22 consumer end-user if it finally ends up in a mixture (as a MiM) for consumer use. The  
23 use types are defined in section 3.4 of this document.

## 24 **5.3 Information on mixture components [Part B.3]**

25 This section provides guidance on which components contained within the mixture have to be  
26 indicated in a submission, and on the information to be provided for each component.

27 The information to be provided on the components of a mixture varies according to the type of  
28 submission the operator has to or has decided to prepare, for example whether it is a standard  
29 submission, a group submission or a limited submission for industrial use only. It can to a certain  
30 extent vary also depending on the knowledge the submitter has on the mixture content. This  
31 section provides guidance on the information required in each case.

### 32 **5.3.1 General requirements [B.3.1]**

33 Ideally, the full composition of the mixture should be indicated. Both hazardous and non-  
34 hazardous components may manifest adverse effects on human health after, for example,  
35 unintended uses. Therefore, poison centres and emergency response personnel may  
36 potentially need information on all components.

37 Nevertheless, for practical reasons components do not legally need to be indicated when  
38 present in the mixture below certain concentration thresholds. Furthermore, in the case of a  
39 mixture for industrial use only, for which a limited submission is made (see section 4.4 of this  
40 guidance), information on composition may be limited to the information available in the safety  
41 data sheet for that mixture (see section 5.3.4).

42 For each component that is required to be listed (see section 5.3.2), the following is to be  
43 specified in the submission:

- 44 • Its chemical identity (see 5.3.3 below), and
- 45 • Its concentration (exact concentration or range – see 5.3.3)

1 Furthermore, the classification of the component is normally required, except when certain  
2 conditions apply (see section 5.3.3).

3 It is not allowed in a submission to list a component which is not present in the mixture, or in  
4 at least one mixture in a group of mixtures in the case of a group submission (except for the  
5 specific derogation for perfume or fragrance components under section 5.4).

### 6 **5.3.2 Components subject to submission requirements [B.3.3]**

7 A component of a mixture can be one of the following:

- 8 • A **substance**, as defined in Article 2(7) of CLP (see section 2);
- 9 • A **mixture in mixture (MiM)** – i.e. a mixture (as defined in Article 2(8) of CLP; see  
10 section 2) used in the formulation of a second mixture that is placed on the market and  
11 the subject of the current submission.

12 To be noted that a “generic product identifier” can be used to indicated certain components;  
13 this is explained later in this section. It is important to underline that for the purposes of  
14 Annex VIII, the term “component” with reference to the mixture subject of the submission, is  
15 used in this guidance to indicate any of the following:

- 16 • a substance,
- 17 • a MiM
- 18 • a substance or mixture indicated with a generic product identifier.

19 Normally, the substances contained in a MiM should be reported individually, as for all other  
20 substances. When the composition of the MiM is fully known, its components should be  
21 considered as components of the final mixture and indicated accordingly. However, if the  
22 submitter does not have access to information on the full composition of the MiM, it is possible  
23 to report the MiM as such in the submission, together with the known components. For further  
24 information, see section 5.3.3 below.

25 A component, whether a substance or a MiM, must be included in the submission when it is:

- 26 1. Classified as hazardous on the basis of physical or health effects, and either
  - 27 – Present in a concentration equal to or greater than 0.1%; or
  - 28 – Identified and present at concentrations below 0.1% - unless the submitter can  
29 demonstrate that it is irrelevant for the purposes of emergency health response  
30 and preventative measures;
- 31 2. Not classified as hazardous on the basis of physical or health effects, when identified  
32 and present at concentrations equal to or greater than 1%. This includes components  
33 not classified or classified for environmental hazard only.

34 ‘*Identified*’ means that the submitter knows the component is present, for example because he  
35 has added it intentionally or it has been communicated to him by a supplier in, for example a  
36 safety data sheet. Submitters are not legally required to analyse their mixtures to determine  
37 the presence of components. Nevertheless, it is recommended to make an effort in actively  
38 seeking missing information from their suppliers, as it may be important for the activities of  
39 the emergency responders.

1 There is no specific scientific method to demonstrate the irrelevance of a substance or mixture  
2 for an emergency health response. The decision not to indicate a component, which is present  
3 below 0.1%, should be based on considerations which include the hazard type (e.g. none of  
4 the hazard classes considered to be of major concern), relevance of the route of exposure (e.g.  
5 the substance is classified for inhalation only but its physical state does not allow inhalation),  
6 concentration (e.g. trace levels can normally be disregarded), and possible interaction with  
7 common treatments. When a Specific Concentration Limit (SCL)<sup>47</sup> exists for a substance, this  
8 may be used as a basis to conclude on the irrelevance of the substance (e.g. substance to be  
9 considered as relevant when the SCL < 0.1% and the substance concentration is between SCL  
10 and 0.1 %). There is no obligation to include the justification in the submission. This can be  
11 the object of a "reasoned request" by the appointed body if it decides so (see section 7.2).

12

### 13 **5.3.3 Information required on components**

#### 14 **A) Identification of the components [B.3.2]**

15 **Substances** in a mixture must be identified in accordance with Article 18(2) of the CLP  
16 Regulation:

- 17 - name and an identification number as given in Part 3 of Annex VI to CLP;
- 18 - if the substance is not included in Part 3 of Annex VI to CLP, a name and an  
19 identification number as they appear in the Classification and Labelling (C&L)  
20 Inventory;
- 21 - if the substance is neither included in Part 3 of Annex VI to CLP nor in the C&L  
22 Inventory database, the CAS number and the IUPAC name, or the CAS number and  
23 another international chemical name, for example the name in INCI nomenclature,  
24 where applicable; or
- 25 - if no CAS number is available and none of the above apply, the IUPAC name or another  
26 international chemical name, for example the name in INCI nomenclature where  
27 applicable.

28 An INCI name, a colour index name or another international chemical name may also be used,  
29 provided the chemical name is well known and unambiguously defines the substance identity.  
30 The chemical name of substances for which an alternative chemical name has been allowed in  
31 accordance with Article 24 of CLP must be provided as well.

32 As regards **mixtures in mixtures (MiMs)**, information on the substances contained in a MiM  
33 must be provided:

- 34 • As a rule, in accordance with what is stated about substances above. Substance  
35 components of a MiM (when the composition of the MiM is fully known) should be  
36 regarded as components of the final mixture. Information regarding same substances  
37 (originating from MiM and/or on their own) should be presented in aggregated form.  
38 Where MiM components or substances are the same (i.e. have the same chemical  
39 identity) but are classified differently by different suppliers, it is recommended that the  
40 submitter contacts the suppliers to investigate the reasons for such difference with the  
41 aim to agree on a common classification.
- 42 • Alternatively, if the submitter does not have access to information on the full

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<sup>47</sup> SCL are assigned to substances according to Article 10 of CLP and are available in Annex VI or/and in the C&L Inventory.

composition of the MiM, this must be identified by means of its product identifier i.e. trade name or designation (according to Article 18(3)(a) of CLP), together with its concentration (range) and UFI, when available (see point C below for information about concentration and classification). Also all known MiM components must be provided (e.g. based on the SDS) in separated form, i.e. not aggregated<sup>48</sup>. It should be noted that, if the full composition is not known, a mixture purchased from different suppliers who assign different classifications cannot be considered to be chemically the same mixture. Enforcement authorities may enquire how the duty holders have complied with this legal condition for lower information requirements.

- As a last resort, in the absence of a UFI and of the possibility to obtain it from the supplier, the safety data sheet of the MiM must be provided, as well as the name, email address and telephone number of the MiM supplier. This scenario was envisaged to address temporarily the issues that may occur during the transition period until 2025, when it comes to communication in the supply chain. It is expected that after 2025, all compositional information is provided within the two above scenarios. If a submitter does not receive the UFI of the MiM from their supplier, this does not discharge the notifier from their legal obligations as regards information provision on (known) components. Such information may be, for example, “accessible” upon request; the duty holders would then have met the legal condition if they demonstrates that they contacted the suppliers by email which replied that the requested information cannot be provided because it is confidential. Enforcement authorities may enquire about how the duty holders have complied with this legal condition for lower information requirements (no access to information).

In the absence of UFI and in the absence of SDS (for mixtures not classified for any hazards, where no obligations to create UFI and provision of SDS exist), the submitter should retrieve information available from other sources (e.g. CAS number, name of main component(s) used when purchasing, etc.).

**Example 17:** Aggregation of components from different sources

A company purchases 2 mixtures (MiMs) and 2 substances from different suppliers to formulate their product SuperClean which they intend to place on the EU market.

The company has knowledge of the full composition of these ingredients (see table below). Same substances are included in the final mixture as components of the MiMs X and Y as substances as such (1 and 2).

| Ingredients purchased by Company A | Concentration in final mixture | Composition   |
|------------------------------------|--------------------------------|---|
| Mixture X (MiM X)                  | 20%                            | Substance 1 - 30%<br>Substance 3 – 40%<br>Substance 4 – 30% |
| Mixture Y (MiM Y)                  | 30%                            | Substance 2 – 15%<br>Substance 3 – 25%                      |

<sup>48</sup> In case the composition of the MiM is not fully known, information should be provided for each known component separately, in order to reduce the risk of confusing information for emergency responders.



|             |     |                   |
|-------------|-----|-------------------|
|             |     | Substance 5 – 60% |
| Substance 1 | 5%  | Na                |
| Substance 2 | 10% | Na                |
| Water       | 35% | Na                |

1  
2  
3  
4  
5  
6

The company will indicate in the submission the components of their final mixture in an aggregated form. The concentration of each substance will refer to the final mixture SuperClean:

| Component   | Concentration in final mixture                           |
|-------------|--|
| Substance 1 | $6 (20\% \times 30\%) + 5 = 11\%$                        |
| Substance 2 | $4.5 (30\% \times 15\%) + 10 = 14.5\%$                   |
| Substance 3 | $8 (20\% \times 40\%) + 7.5 (30\% \times 25\%) = 15.5\%$ |
| Substance 4 | $6\% (20\% \times 30\%)$                                 |
| Substance 5 | $18\% (30\% \times 60\%)$                                |
| Water       | 35%  |

7

8 A **generic product identifier** – “perfumes”, “fragrances” or “colouring agents” - can be used  
9 to identify one or several components of the mixture, if they are used exclusively to add  
10 perfume, fragrance or colour, respectively, to the mixture. The generic product identifier is  
11 used instead of the actual chemical identity of the relevant component(s), and may be used  
12 where the following conditions are met:

- 13 • The relevant component(s) is/are not classified for any health hazard, and
- 14 • The total concentration of the components covered by the generic product identifier  
15 does not exceed:
  - 16 ○ 5% for the sum of perfumes and fragrances;
  - 17 ○ 25% for the sum of colouring agents

18 Mixtures whose composition differs only in components which can be identified by the same  
19 generic product identifier, can be included in the same submission. Such mixtures may be  
20 placed on the market under multiple trade names which can be also indicated in the same  
21 submission.

22 Note: using generic product identifiers is optional and at the discretion of the submitter.

### 23 **B) Concentration and concentration ranges of the mixture components [B.3.4]**

24 The regulation provides different provisions for mixture components (substances and MiM) that  
25 are considered of ‘major’ concern and ‘other’ components. This distinction is defined in section  
26 3.4 of Part B of Annex VIII. The submitter is required to provide the concentration or

1 concentration ranges of each component according to the hazard class as described below.  
 2 In case of MiM for which the composition is fully known, the concentration of its components  
 3 should refer to the final mixture. In case the same components comes from different sources  
 4 (e.g. as component of a MiM and as single substance), the information should be provided in  
 5 aggregated form<sup>49</sup>.

6 *B.1) Hazardous components of major concern for emergency health response and preventative*  
 7 *measures*

8 When mixture components are classified in accordance with this Regulation for at least one of  
 9 the hazard categories listed below, their concentration in a mixture must be expressed as  
 10 exact percentages, in descending order by mass or volume:

- 11 – acute toxicity, Category 1, 2 or 3
- 12 – specific target organ toxicity (Single exposure, Category 1 or 2)
- 13 – specific target organ toxicity (Repeated exposure, Category 1 or 2)
- 14 – skin corrosion, Category 1, 1A, 1B or 1C
- 15 – serious eye damage, Category 1

16 As an alternative to providing concentrations as exact percentages, a range of percentages  
 17 may be submitted in accordance with Table 1 in Part B of Annex VIII (reported in Table 2  
 18 below), in descending order by mass or volume.

19 Where the exact concentration is higher than 1%, the upper and lower limits of the  
 20 concentration bands could be rounded to a maximum of one decimal; where the exact  
 21 concentration is lower than or equal to 1%, a maximum of two decimals could be used.

22 **Table 2: Concentration ranges applicable to hazardous components of major concern**  
 23 **for emergency health response (substances or MiM) - Table 1 in Part B of Annex VIII**

| Concentration range of the hazardous component contained in the mixture (%) | Maximum width of the concentration range to be used in the submission |
|---|---|
| ≥ 25 - < 100  | 5% units  |
| ≥ 10 - < 25   | 3% units  |
| ≥ 1 - < 10  | 1% unit   |
| ≥ 0,1 - < 1   | 0,3% units  |
| > 0 - < 0,1   | 0,1% units  |

24

25 **Example 18:** Concentration ranges for components of "major" concern

26 In the case of a substance (hazardous component of "major" concern) in a mixture with an  
 27 exact concentration of 26%, the submitter can choose among different ranges to report,  
 28 provided that the exact concentration is comprised within this range and the maximum width

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<sup>49</sup> This should not be done in case the composition of the MiM is only partially known as it may lead to misleading information for poison centres and emergency responders.

of the concentration range is 5% units: 21-26%, 22-27%, 23-28%, 24-29%, 25-30%, 26-31%. Also narrower ranges can be applied such as 25-27% etc.

*B.2) Other hazardous components and components not classified as hazardous*

The concentration of components classified for hazard classes not listed above or components not classified as hazardous should be expressed, in accordance with Table 2 in Part B of Annex VIII (reported in Table 3 below), as concentration ranges in descending order by mass or volume. As an alternative, the exact concentration can be provided.

Where the exact concentration is higher than 1%, the upper and lower limits of the concentration bands could be rounded to a maximum of one decimal; where the exact concentration is lower than or equal to 1%, a maximum of two decimals could be used.

All components classified as hazardous on the basis of their health or physical effects may need to be included in the submission even if present in concentrations below 0.1% if identified, unless demonstrated to be irrelevant for emergency health response and preventative measures (see section 5.3.2 above).

**Table 3: Concentration ranges applicable to other hazardous components and components not classified as hazardous (substances or MiM) – Table 2 in Part B of Annex VIII**

| Concentration range of the component contained in the mixture (%) | Maximum width of the concentration range to be used in the submission |
|---|---|
| ≥ 25 - < 100  | 20% units   |
| ≥ 10 - < 25   | 10% units   |
| ≥ 1 - < 10  | 3% units  |
| > 0 - < 1   | 1% unit   |

**Example 19:** Concentration ranges for components not of “major” concern

In the case of a substance (not classified or classified as hazardous but not of major concern) in a mixture with an exact concentration of 6%, the submitter can choose among different ranges provided that the exact concentration is comprised within this range and the maximum width of the concentration range is 3% units: 3-6%, 4-7%, 5-8% or 6-9%. Also narrower ranges can be applied such as 5-6%.

**Special case: perfume or fragrance components**

In the case of perfume or fragrance components that are not classified as hazardous or are classified only for skin sensitisation Category 1, 1A or 1B or aspiration toxicity, submitters are not obliged to provide information on their concentration, as long as the total concentration of such perfume or fragrance component does not exceed 5%.  
For colouring agents with a generic product identifier, Table 3 above applies.

**C) Classification of mixture components (substances and MiM) [B.3.5]**

The classification for health and physical hazards of the mixture components must be provided. This includes hazard classes, categories and statements of, at least, all the identified substances which are referred to in Point 3.2.1 of Annex II to the REACH Regulation (requirements for the compilation of SDSs). Point 3.2.1 lists the criteria for identifying the component substances that have to be indicated in the SDS of a mixture itself classified as

1 hazardous<sup>50</sup>.

2 In other words, at least for all the component substances that would need to be indicated on  
3 the SDS of the mixture, their classification is to be provided in the submission. Annex II to  
4 REACH also includes an obligation to provide information on substances classified for  
5 environmental hazards only. For the purposes of Annex VIII, for components classified for  
6 environmental hazards only, the classification does not need to be indicated (although it can  
7 be indicated on a voluntary basis).

8 In the cases where the mixture for which submission needs to be made contains one or more  
9 MiM(s) (for which full composition is not known), the notifier should provide the classification  
10 of the MiM itself. In this case, the classification of the components of the MiM(s) is not  
11 required.

12 In case the MiM composition is fully known, the classification for health and physical hazards of  
13 the substances contained in the MiM should be indicated following the rules above.

14  
15 Information on classification for environmental hazards is not required.

16 Components identified via a generic product identifier may present physical hazards.  
17 Nevertheless the classification of such components (even when the same generic product  
18 identifier covers several components) does not need to be indicated.

19 **Example 20: Use of Generic Product Identifiers**

20 In option A, all components are included in the submission with the 'chemical name',  
21 health/physical hazard classification and concentration in the mixture (either a concentration  
22 range or an exact concentration). There are eight fragrance components (1-8) and three other  
23 components (A,B,C).

24 The use of generic product identifiers is illustrated in the option B below where  
25 fragrance/perfume components are grouped. Note: the indicated concentrations, classifications  
26 and number of components are chosen with the sole purpose of explaining the requirements.  
27

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<sup>50</sup> See ECHA's *Guidance on the compilation of safety data sheets*.

| OPTION A – ALL COMPONENTS INDICATED WITH A 'CHEMICAL NAME' |                        |                |
|--|------------------------|----------------|
| Components   | Classification         | Concentrations |
| Chemical name component A                                  | not classified         | 60-80%         |
| Chemical name component B                                  | not classified         | 13%            |
| Chemical name component C                                  | major concern          | 11-14%         |
|  |                        |                |
| Fragrance chemical name 1                                  | not classified         | 1-4%           |
| Fragrance chemical name 2                                  | not classified         | 1%             |
| Fragrance chemical name 3                                  | not classified         | 0.5%           |
| Fragrance chemical name 4                                  | acute toxicity, cat 1  | 0.3-0.6%       |
| Fragrance chemical name 5                                  | skin corrosion, cat 1C | 2-3%           |
| Fragrance chemical name 6                                  | skin sens. cat. 1      | 2%             |
| Fragrance chemical name 7                                  | aspiration toxicity    | 3-6%           |
| Fragrance chemical name 8                                  | not classified         | 4%             |

1 This composition can alternatively also be submitted as presented in option B (below).  
 2 Fragrance components 1 to 3 are indicated with a generic product identifier. This is allowed  
 3 since these components are not classified for a health hazard and the total concentration of the  
 4 components covered by the given generic product identifier does not exceed 5% [B.3.2.3].  
 5 'Fragrance chemical name 4 to 7 cannot be indicated with a generic product identifier because  
 6 these components are classified for a health hazard.

| OPTION B – SOME COMPONENTS INDICATED WITH A GENERIC PRODUCT IDENTIFIER |                        |                             |
|--|------------------------|-----------------------------|
| Components   | Classification         | Percentage                  |
| Chemical name component A  | not classified         | 60-80%                      |
| Chemical name component B  | not classified         | 13%                         |
| Chemical name component C  | major concern          | 11-14%                      |
|  |                        |                             |
| <i>Fragrances</i>  | not classified         | 3%, 2-5% or 'not indicated' |
| Fragrance chemical name 4  | acute toxicity, cat 1  | 0.3-0.6%                    |
| Fragrance chemical name 5  | skin corrosion, cat 1C | 2-3%                        |
| Fragrance chemical name 6  | skin sens. cat. 1      | 2% or 'not indicated'       |
| Fragrance chemical name 7  | aspiration toxicity    | 3-6%                        |
| Fragrance chemical name 8  | not classified         | 4%                          |

7 **Additional notes to the example:**

- 8 • 'Fragrance chemical name 1' was indicated in option A with a concentration range of 1-  
 9 4%. The actual concentration apparently was 1.5% (only known to the submitter) so  
 10 the total concentration is 1.5+1+0.5=3%.
- 11 • Not all non-classified fragrances can be grouped within the same generic product  
 12 identifier because if 'fragrance chemical name 8' is included, the total concentration is  
 13 7%. Other non-classified fragrance component must be indicated individually with their  
 14 chemical name.  
 15

- It would also have been possible to, for example, indicate 'fragrance chemical name 2' and 'fragrance chemical name 8' with a generic product identifier "fragrances" since the total concentration does not exceed 5%. In that case the other non-classified fragrance components (1 and 3) must be indicated individually with their chemical name.
- On the indicated concentration:  
The generic product identifier can be indicated with an exact concentration (the sum of the components covered by the same generic identifier, 3% in the example) or a range according to table 2, for example 2-5% (3% units bandwidth allowed; with a maximum of 5%). Alternatively it is allowed to not indicate the concentration at all. For fragrance components that are not classified or only classified for skin sensitisation or aspiration hazard concentration is not required provided that the total concentration does not exceed 5% [B.3.4.2]. Since the actual concentration of the generic product identifier is 3%, it is possible to additionally not indicate the concentration of 'Fragrance chemical name 6' to reach the maximum of 5% (or alternatively of "Fragrance chemical name 7" as long as the limit of 5% is not exceeded).

#### 5.3.4 Limited submission [B.3.1.1]

When a company decides to opt for a limited submission (possible for mixtures intended for industrial use only) the list of components to be provided may be limited to that included in Section 3.2 of the SDS. Also the information to be provided on the concentrations of such components may be limited to that contained in the SDS.

Detailed information on the compilation of the SDS, and in particular of Section 3, is available in the ECHA's *Guidance on the compilation of safety data sheets*<sup>51</sup>.

In practice, the information provided in this case will be less detailed than a standard submission and the poison centre will not have access to the full composition of the mixture. For example, Annex II to REACH (on the compilation of SDS) does not require the indication of not classified components, and sets for the hazardous components to be indicated concentration thresholds and ranges which are less strict than Annex VIII to CLP (e.g. hazardous components may need to be included in a standard submission even if present in concentration <0.1%).

#### 5.4 Group submission [A.4]

Information on multiple mixtures with limited differences in the composition can be provided in the same submission: this is referred to as a 'group submission'. The general conditions under which such a 'group submission' is allowed are specified in Section 4, part A of Annex VIII.

Mixtures can be grouped in the same submission if they:

- have the same classification for health and physical hazards (this means that a difference in classification for environmental hazard is allowed);
- belong to the same product category (see section 4.3 for details on the EuPCS);
- have very similar composition (see section 5.4.2 for details);

---

<sup>51</sup> Available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

- 1           • the same components are reported in the same concentration or concentration  
2           range.

3 Besides substances indicated with their own chemical name, as explained in section 5.3, the  
4 mixtures' components can include substances, MiM, and components which are allowed to be  
5 indicated with 'generic product identifiers' (see section 5.3.3).

6  
7 All mixtures in the group must contain the same components, except for perfume or fragrance  
8 components, as referred to in point A.4.3 of Annex VIII. The latter can differ between mixtures  
9 in the group under certain conditions (see section 5.4.2 below).

10  
11 Under the conditions described above, group submission is possible for:

- 12           • Similar mixtures that are marketed under different trade names. Those might be  
13           intended for a different user group, for example 'consumer use' and 'professional use'.  
14           • Mixtures with compositions that differ, under certain conditions, in fragrances and/or  
15           perfumes. These would be 'product variants' (possibly marketed under different trade  
16           names), for example detergents with a difference in fragrances.

17 Note: the grouped mixtures all have to be placed on the market by the same importer or  
18 downstream user (and their distributors). A group submission can only include the details of  
19 one 'legal submitter' (i.e. duty holder). It is not possible to group mixtures that are placed on  
20 the market by different duty holders.

21  
22 Ultimately, the difference between a standard and a group submission concerns the possibility  
23 to group mixtures with variation in fragrances and/or perfumes which cannot be indicated with  
24 a generic product identifier. As explained earlier in this section, also in a standard submission  
25 multiple trade names can be included, as long as the composition of the mixture remains the  
26 same.

27  
28 Note: The decision whether to provide a standard or group submission (when the conditions  
29 are fulfilled) lays with the duty holder and could be based on the specific portfolio. Group  
30 submission is an option provided to facilitate the fulfilment of the obligations: the duty holder  
31 may always decide to submit a standard submission for each product without grouping it with  
32 other products.

### 5.4.1 Information to be provided in a group submission

Information described in part B of Annex VIII should be provided for each of the mixtures in the group.

The information provided on mixture components in a group submission should apply to all the mixtures in the group, except for perfumes or fragrances that may only apply to some mixtures in the group under certain conditions (see section 5.4.2 below).

Most of the information will be the same but there might be a difference in:

- 'Product identifiers of the mixture': a group submission (as well as a standard submission) may cover mixtures placed on the market with different trade names and/or to which different UFI's could be assigned.
- 'Additional information' items listed in Part B, Section 2.4, of Annex VIII:
  - Colour and physical state of the mixture;
  - pH;
  - Types and sizes of the packaging;
  - Use types (consumer, professional, industrial) as described in section 3.4 of this Guidance.

Trade names, colour, packaging, use types and UFI's should be indicated for every individual product in the group. This information may be useful for the emergency responders in order to promptly identify the relevant information for the specific product.

Nevertheless for the colour, a limited range of standard types can be used (no need to indicate the exact shade). Exceptionally and for practical reasons, a generic indication of the colour field can be accepted for paints and other similar categories for example inks, where high numbers of products with great colour variability can be included in the same group submission (provided they are not classified).

Regarding the packaging, the specific type is potentially relevant to identify the appropriate emergency response measures to assist with possible product identification. This information should be provided for each mixture of the group placed on the market with a specific trade name.

The pH value can be indicated for the group as a whole; a range applicable to the whole group can be used. Where the pH value is particularly low or high (i.e. <3 or >10), the range to be indicated should not be bigger than one unit (e.g. 2.5 – 3.5).

### 5.4.2 Mixture components in a group submission

Mixtures in a group submission should contain the same components in the same concentration or concentration range, except for perfumes and fragrances components. Those components may only differ between the mixtures of the group under the conditions described below (point A.4.3 and B.3.1 of Annex VIII). The total concentration of all perfumes and fragrances in each mixture of the group cannot exceed 5%. In case the concentration of fragrances or perfumes in a mixture is above this threshold, the mixture cannot be included in the same group submission.

The intention of this rule is to allow grouping of the mixtures only if their compositions are very similar (and hence the toxicological information does not vary). This means that for a maximum of 5% of the composition, the mixtures' compositions may differ in perfumes or/and fragrances content.

It is to be underlined that the 5% must include all the fragrances/perfumes in the mixture (i.e.



1 regardless of whether they are present in all the mixtures or the group, or are those differing  
2 between the mixtures). In practice this means that if the mixtures contain common  
3 fragrances/perfumes indicated by chemical name or GPI, the 5% threshold will have to include  
4 those common fragrances/perfumes, leaving less than 5% for the varying  
5 fragrances/perfumes.

6 The perfumes and fragrances contained in each mixture of the group must be given by  
7 providing a list to identify the perfumes or fragrances they contain, including their  
8 classification.

9 The information required on the mixture composition in a group submission is illustrated by  
10 examples 21 and 22. References to the relevant legal text are made in the notes to the  
11 examples (in square brackets) to indicate compliance with the requirements on group  
12 submission as well as with requirements on component identification/information where  
13 relevant for grouping. For detailed guidance on component identification and information  
14 requirements, please see section 5.3 of this guidance document.

15  
16 It is important to note that these examples are presented in a simplified form with the sole  
17 purpose of illustrating the requirements for group submission. In the examples different  
18 formats are used to present the information, but the same principles apply.

19 **Example 21:** Grouping of mixtures with difference in perfume/fragrance components

20 Mixtures in the group have a difference in some fragrance/perfume components that are  
21 classified for a health hazard (therefore those components cannot be indicated with a 'generic  
22 product identifier').

| <b>GROUPING OF MIXTURES WITH DIFFERENCE IN PERFUME/FRAGRANCE COMPONENTS</b>   |   |                        |
|---|---|------------------------|
| <u>UFIs:</u><br>- N200-U0CW-5009-QWHJ<br>- G500-C029-F00T-D83M<br>- P800-U0RP-S009-1KPP<br><u>Classification:</u> #<br><u>Product Category:</u> # | <u>Product names:</u><br>- Trade name 1<br>- Trade name 2 |                        |
| <b>Components</b>   | <b>Percentage</b>   | <b>Classification*</b> |
| Chemical name component A   | 60-80%  | Not classified         |
| Chemical name component B   | 7-10%   | Other                  |
| Chemical name component C   | 11-14%  | Major concern          |
| Chemical name component D   | 1-2%  | Major concern          |
| Perfumes (Generic product identifier)   | <5%   | not classified         |
| Fragrance chemical name 1   | 1-4%  | other                  |
| Fragrance chemical name 2   | 0.3-0.6%  | major concern          |
| Fragrance chemical name 3   | 2-3%  | major concern          |
| Fragrance chemical name 4   | 1-3%  | other                  |
| ‘Perfume MiM’<br>UFI: A67T-VHG2-DMM4-NH2A   | 1-4%  | Other                  |
| <b>MIM's known components:</b>  |   |                        |
| <u>MIM component A</u>  | 2-4 % (in MiM)  | <i>[Optional]</i>      |
| <u>MIM component B</u>  | 8-12 % (in MiM)   | <i>[Optional]</i>      |

1

2 Since fragrances and perfumes vary between the mixtures contained in the group, a list must  
 3 be provided of the mixtures and the perfumes or fragrances they contain, including their  
 4 classification. This information is contained in the additional list as required in section B.3.1 of  
 5 Annex VIII:

| Name   | Fragrance or perfume                 | Classification*           |
|--|--------------------------------------|---------------------------|
| Trade name 1                                     | Fragrance chemical name 1            | other                     |
| UFIs: N200-U0CW-5009-QWHJ<br>G500-C029-F00T-D83M | Fragrance chemical name 3            | major concern             |
|  | 'Perfume MiM'<br>A67T-VHG2-DMM4-NH2A | other                     |
| Trade name 2                                     | Fragrance chemical name 2            | major concern             |
| UFI: P800-U0RP-S009-1KPP                         | Fragrance chemical name 4            | other (skin sens. cat. 1) |
|  | Perfumes                             | not classified            |

\* In this example classifications are indicated with three categories: 'major concern' (list of classifications in B3.4.1), 'other' (all other hazard classifications) and 'not classified'.

Compliance with Annex VIII requirements:

- All mixtures in the group have the same components in the same concentration or concentration ranges [A4.2], except for the components 'fragrance chemical name 1 - 4', 'Perfume MiM' and the perfumes indicated with the generic product identifier "perfumes" that are at least present in one of the mixtures [A4.3].
- The difference between the mixtures concerns only perfumes or fragrances and 'the total concentration of all perfumes and fragrances contained in each mixture does not exceed 5%' [A.4.3]. This concerns the sum of 'actual concentrations' (which are known to the submitter, see below) of these components while a concentration range is indicated in the submission.
- If the composition of a MiM is only partially known, the UFI has to be provided together with the known components [B.3.2.2]. Classification of MiM's components can be provided on voluntary basis.
- Since the MiM composition is not fully known, information on the concentration of known MiM components refers to the MiM itself.
- The specific concentration of the components included under GPI "Perfumes" does not have to be indicated provided that the total concentration of those perfumes or fragrances does not exceed 5%.
- While classification of the mixture is a mandatory information requirement, the classification of the known components of a MiM it is not (but it useful information which can be provided on voluntary basis).

**Trade name 1:**

Fragrance chemical name 1 - indicated 1-4% - actual concentration 1.2%.

Fragrance chemical name 3 - indicated 2-3% - actual concentration 2.1%.

Perfume MiM - indicated 1-4% - actual concentration 1%.

The actual concentration of fragrance and perfume components in the mixture is 4.3%.

**Trade name 2:**

Fragrance chemical name 2 - indicated 0.3-0.6% - actual concentration 0.4%.

Fragrance chemical name 4 - indicated 1-3% - actual concentration 1.4%.

Perfumes – not indicated – actual concentration 2%

The actual concentration of fragrance and perfume components in the mixture is 3.8%.

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**Example 22:** Grouping of mixtures with difference in perfume/fragrance components

**GROUP SUBMISSION**

UFI: C4P7-GHVS-ED8M-42DH

Product category: All-purpose (or multi-purpose) non-abrasive cleaners

CLP classification: Serious eye damage cat.1 + Skin sensitiser cat.1

Product trade names: ABC, BCD, CDE

**Product- trade name ABC + Product- trade name BCD + Product-trade name CDE**

|                           | Components          | Classification                | Concentration |
|---------------------------|---------------------|-------------------------------|---------------|
| <b>COMMON INGREDIENTS</b> | Surfactant 123      | Serious eye damage cat.1      | 5-6%          |
|                           | Surfactant 456      | Serious eye damage cat.1      | 8-9%          |
|                           | Soap xyz            | Not classified                | 2-5%          |
|                           | Sodium carbonate    | Serious eye irritation cat. 2 | 7-10%         |
|                           | Processing aid xxx  | Not classified                | 1-2%          |
|                           | Water               | Not classified                | 66-76.4%      |
|                           | Perfumes components | As attached or not classified | up to 5%      |

**Variant in perfumes:**

**Product- trade name ABC**

| Components        | Classification   | UFI and known components   | SDS      | Concentration               |
|-------------------|--|--|----------|-----------------------------|
| Perfume mixture a | MIM: Skin sens. Cat. 1<br>Known component 1: #<br>Known component 2: # | UFI A67T-VHG2-DMM4-NH2A + known component 1+known component 2 + ...etc | -        | <i>Not needed [B.3.4.2]</i> |
| Perfume mixture b | Skin sens. Cat 1B + asp. tox.  | Not available  | Provided | 0.5-1.5%                    |

**Product- trade name BCD**

| Components                               | Classification | UFI            | SDS | Concentration |
|--|----------------|----------------|-----|---------------|
| « Perfume » (Generic Product Identifier) | Not classified | Not applicable | -   | 0.6-2%        |

| Product- trade name CDE                  |                              |                |          |               |
|--|------------------------------|----------------|----------|---------------|
| Components                               | Classification               | UFI            | SDS      | Concentration |
| Perfume mixture b                        | Skin sens. Cat 1B + asp. tox | Not available  | Provided | 0.5-0.9%      |
| « Perfume » (Generic Product Identifier) | Not classified               | Not applicable | -        | 0.1- 1.1%     |

**Notes to the tables of example 22:**

- Total perfume a + perfume b in product- trade name ABC should not exceed 5% [A.4.3].
- Total perfume b + "perfume" (GPI) in product-trade name CDE should not exceed 5% [A.4.3].
- Components of perfume a are included in the submission of this perfume a by a supplier upstream (link with UFI).
- "Perfume" (GPI) does not contain any hazardous component [B.3.2.3].
- The concentration of known MiM components refers to the MiM itself (MiM composition not fully known).

| List of perfumes in Group submission     |                               |   |
|--|-------------------------------|---|
| Perfume name                             | Classification                | Products of the GS where the perfume is present |
| Perfume mixture a                        | Skin sens. Cat 1              | Product- trade name ABC                         |
| Perfume mixture b                        | Skin sens. Cat 1B + asp. tox. | Products- trade names ABC+CDE                   |
| « Perfume » (Generic Product Identifier) | NC                            | Products- trade names BCD+CDE                   |

## 6. Preparation and submission of information: available tools

The submission of the required information has to be done electronically and using the XML format provided by ECHA [A.3.1]. The tools developed and maintained by ECHA assists both the submitters and the Member States appointed bodies in fulfilling their obligations and perform their tasks. The tools support the preparation of the submission in the correct format, allow the submission of the information and facilitate the distribution of the submitted information to the relevant Member State(s).

### 6.1 UFI generator

The generation of the UFI(s) can be done at any time before the actual submission. It should be preferably done during the mapping and analysis of the portfolio while preparing the submission strategy. Generation and use of UFI is explained in section 4 (in particular subsection 4.2) which addresses the general submission requirements.

### 6.2 XML format

Annex VIII to CLP mandates ECHA to specify, maintain and update the electronic XML-based format that must be used for the submission of the harmonised information [A.6].

1 The use of this format is mandatory and alternatives (e.g. paper submissions or other  
2 electronic formats) are not allowed. The format is harmonised and it applies in all Member  
3 States.

4 ECHA, being strongly engaged with the OECD in international initiatives aiming to promote the  
5 definition and use of commonly agreed formats for the electronic exchange of information on  
6 chemicals, developed the XML format under the IUCLID (International Uniform Chemical  
7 Information Database) project.

8  
9 The format is available for download from ECHA Poison Centre website and its use is free of  
10 charge. The usage of the format and creation of submission files containing required  
11 information can be executed offline using the IT systems available to duty holders.

### 12 13 **6.3 PCN editor for generating IUCLID XML files**

14 ECHA aims at providing the companies with an online editor that allows insertion of data and  
15 creation of XML files using an ECHA web-based application. The online editor does not require  
16 a company to develop IT data management systems and is particularly aimed at facilitating  
17 companies (in particular SMEs) to comply with their obligations under Annex VIII.

### 18 19 **6.4 Submission of information**

20 The IUCLID XML files, once prepared and containing the required information, must be  
21 submitted to the appointed bodies, as stipulated by Article 45(1) CLP. Submissions must be  
22 made to the appointed bodies by electronic means endorsed by them for that purpose. It is at  
23 the discretion of each Member State to define technical means of submission, including the  
24 possibility to 'outsource' this task and allow the submission of information centrally via the PCN  
25 portal provided by the Agency. Submitters are invited to carefully verify the conditions and  
26 instruction for the submission of the information with the countries where the mixture is placed  
27 on the market.

28  
29 The PCN portal provides for industry the following main features:

30 - submissions can be prepared and submitted online using the PCN editor integrated in the  
31 portal;

32 - submissions prepared offline using the XML format can be uploaded to the PCN portal (also in  
33 bulk);

34 - submissions are integrated system-to-system between PCN portal and company IT systems.

35 The PCN portal provides for Member States the following main features:

36 - submissions can be downloaded and integrated into local databases;

37 - submissions can be stored at the database coupled with PCN portal and hosted by the  
38 Agency.

39 Whether the submissions are made by industry and received by Member States centrally via  
40 PCN portal or locally via Member States submission systems, it is still the Member States that  
41 are responsible for any enforcement related to the submission of information, including  
42 compliance with submission deadlines, content, quality and update of the submissions etc.  
43 Appointed bodies remain responsible for the verification of the quality of the information  
44 submitted.

45

## 1 **6.5 Fees**

2 The usage of XML formats, UFI generator, EuPCS and PCN Portal provided by the Agency is  
3 free of charge.

4 However it needs to be noted that a fee may be levied in each Member State for each  
5 submission. It is at the discretion of the competent authority of the Member State where the  
6 submission is to be made to decide whether fees are applicable for submission to the national  
7 appointed body/bodies.

## 8 **7. Post-submission**

### 9 **7.1 General introduction**

10 Successful submission of the information to the appointed body is the basic requirement before  
11 placing the product containing the mixture on the market of the relevant Member State. This  
12 requires the submission to be compliant with the requirements of Annex VIII.

13 It is to be noted that some of the Member States currently require additional information that  
14 goes beyond the scope of Article 45 and Annex VIII to be submitted before placing the product  
15 on their market. This information is normally requested within different legal frameworks and  
16 for purposes potentially different from those described in this guidance (see section 7.3). No  
17 additional information can be requested under national legislation to that specified in Annex  
18 VIII for the purposes provided for under Article 45. The XML format defined for the purpose of  
19 Annex VIII implementation does not foresee such additional requirements.

20 Submitters have to make sure that the submitted information is constantly up-to-date in order  
21 to ensure that the poison centres have the relevant information at their disposal. Changes  
22 which trigger a mandatory update of the submission are detailed in section 7.4.

23

### 24 **7.2 Additional requests by appointed bodies**

25 Appointed bodies may perform, either on a regular basis or following specific criteria or “alerts”  
26 (e.g. under indication of the poison centre), a quality check of the submitted information  
27 (expected within a short timeframe after the submission). Should the appointed bodies identify  
28 areas that are deficient, unclear or maybe considered conflicting, they could contact the  
29 company who made the submission and request clarification or justification for any open or  
30 conflicting areas (e.g. regarding the quality of toxicological information provided or its  
31 consistence with other information). These checks are related to the overall compliance of the  
32 submitted information with the requirements of the Annex VIII.

33 Additionally, according to point A.3.2 of Annex VIII, an appointed body can make a “reasoned”  
34 request for additional information or clarification if this is necessary to carry out its tasks under  
35 Article 45. In the case of an emergency, unforeseeable situations or in general on an *ad hoc*  
36 basis, appointed bodies may request under point A.3.2 other information (potentially  
37 exceeding the boundaries of Annex VIII) which is necessary to perform the activities under  
38 Article 45 (see section 7.3 below). These requests, should be justified, limited to particular  
39 cases, cannot be made on a systematic basis and can occur at any point in time.

40 Examples of a reason for requesting additional information could be the following:

- 41 - A need for access to more detailed data, based on which the toxicological information  
42 was prepared by the submitter.
- 43 - To evaluate the correctness of assigned product category according to EuPCS.

- To enquire about possible presence of non-classified components which are not required to be included in the submission (low concentration thresholds) but could be relevant to assess the hazard (e.g. synergistic effects) or the potential exposure (e.g. bittering agents).
- To enquire about packaging information not included in the submission following incidents involving children (e.g. child-resistant fastening).

### 7.3 Use of submitted information

As indicated in Article 45 of CLP, appointed bodies have to ensure that the submitted information is used only to:

- (a) meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; and
- (b) where requested by the Member State, undertake statistical analysis to identify where improved risk management measures may be needed.

Appointed bodies or poison centres may undertake statistical analysis of the submitted information to identify where improved risk management measures may be needed. These data can help to identify particular trends in incidents or to adjust the focus of preventative actions.

#### 7.3.1 Security and confidentiality of the submitted information

Information submitted to appointed bodies may contain sensitive and confidential. Systems which handle this information should be designed to follow strict security standards. The information can be used by personnel authorised by the appointed bodies.

Appointed bodies and poison centres have to provide all requisite guarantees for maintaining the confidentiality of the information received. In the event of emergency they are required to provide health response without disclosing directly confidential business information.

### 7.4 Keeping information up to date

#### 7.4.1 Introduction

This section provides guidance on when the information submitted has to be updated and covers in particular Section 4, Part B of Annex VIII. It covers also voluntary updates following changes not listed under B.4.1. After a submission, changes may be made to the submitted mixture or new information about it may become available. It is necessary to ensure that the information submitted to the appointed body is relevant and up-to-date for every product being and having been placed on the market. This will make sure that adequate advice can be given in poisoning accidents by poison centres and medical services. The legal text indicates which changes trigger specific actions from the submitter.

It should be noted that existing submissions made in accordance with national rules are valid until 1 January 2025 (see section 3.5). However, if a change described in Section 4, Part B takes place before that date (and after the relevant deadline according to the use type described in section 3.4), a submission update has to be made in accordance with Annex VIII.



## 7.4.2 Update rules according to Annex VIII

The updating rules apply to both new submissions in the harmonised format and to mixtures already notified in accordance with the existing national rules before the entering into force of Annex VIII (see section 3.5.1 above).

According to Section B.4.1 of Annex VIII, a submission update is required when:

- the name of the mixture (the product identifier, e.g. trade name/brand/identification of the mixture) or the UFI is changed, or
- the mixture classification for health or physical hazards changes, or
- relevant new toxicological information that is required in Section 11 of the safety data sheet becomes available on the hazardous properties of the mixture or its components, or
- the composition of the mixture is changed following:
  - a) Addition, substitution or deletion of one or more of the components that needs to be indicated<sup>52</sup>, or
  - b) Change in the concentration range provided in the original submission; i.e. the concentration of a component of the mixture, is changed beyond the concentration range provided in Table 1 and 2 Annex VIII, or
  - c) Change in the exact concentration provided in the original mixture; i.e. the concentration of a component in the mixture is changed beyond the limits indicated in Table 3 of Annex VIII and reported in table 4 below.

Note that whenever changes listed above occur, an update of the submitted information is required before the mixture, as changed, is placed on the market.

### 7.4.2.1 When declaring concentration ranges

Changes in the mixture component concentration ranges, for instance for a hazardous component of major concern (see Table 1 in Part B of Annex VIII), can be illustrated in example 23. The component 'B' present at a concentration of 20.5%, can be reported using a range of 3% (for instance 19.9-22.9%). If the new concentration falls out of this range (e.g. the new concentration is 23.5%), an update of the submission is required and a new UFI has to be created. However, if the change in the concentration stays within the mentioned range (e.g. the new concentration is 22.1%), there is no obligation to update the submission.

#### Example 23: Mixture components with classification of major concern

| MIXTURE COMPONENTS WITH CLASSIFICATION OF MAJOR CONCERN |  |  |   |
|---|--|--|---|
| Component   | Exact concentration in the mixture (%) | Concentration ranges provided in the original submission (%) | New concentration requiring a submission update (%) |
| Comp A  | 3.5                                    | 3.2-4.2  | <3.2 or >4.2  |

<sup>52</sup> To be noted that the substitution of one component (substance or MiM) by another with identical composition and hazard profile (possibly following a change of supplier) does not trigger the need for an update or a new submission.

|        |      |           |                |
|--------|------|-----------|----------------|
| Comp B | 20.5 | 19.9-22.9 | <19.9 or >22.9 |
| Comp C | 76   | 71-76     | <71 or >76     |

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**7.4.2.2 When declaring exact concentrations**

When declaring the exact concentration of mixture components, only limited changes to the exact value are allowed within a certain variation without the need to update. Allowed variations are listed in Table 3 of Annex VIII (see Table 4 below). If the new concentration exceeds the allowed variation, an update is required and a new UFI has to be created. Example 22 illustrates that if a component is present in a mixture in a concentration of 72% when the original submission is made, an allowed variation of  $\pm 5\%$  (or more) of the initial concentration triggers the need to update the submission. Therefore an update is needed if the new concentration is  $<68.4\%$  or  $>75.6\%$ .

**Table 4: Variations of the concentration of components requiring a submission update (Table 3 of Annex VIII)**

| Exact concentration of the component contained in the mixture (%) | Variations ( $\pm$ ) of the initial component concentration requiring a submission update |
|---|---|
| > 25 - $\leq$ 100   | 5%  |
| > 10 - $\leq$ 25  | 10%   |
| > 2,5 - $\leq$ 10   | 20%   |
| $\leq$ 2,5  | 30%   |

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**Example 24:** Mixture submitted with exact concentrations of components

| <b>MIXTURE SUBMITTED WITH EXACT CONCENTRATIONS OF CLASSIFIED COMPONENTS</b> |  |   |   |
|---|--|---|---|
| Component   | Exact concentration provided in the submission (%) | Variations ( $\pm$ ) of component concentration requiring a submission update (%) | New concentration requiring a new UFI (%) |
| Comp D  | 1  | 30  | <0.7 or >1.3                              |
| Comp E  | 5  | 20  | <4 or >6                                  |
| Comp F  | 22   | 10  | <19.8 or >24.2                            |
| Comp G  | 72   | 5   | <68.4 or >75.6                            |

Note: the use of Table 3 of Annex VIII deserves some clarification: the reference concentration to define whether a UFI change is required should be always the original one. This allows avoiding the situation where many small changes (followed by voluntary updates) and not requiring a UFI update lead to the situation where eventually the concentration has changed significantly from the original one, yet the UFI remains the same.

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### 1 7.4.3 Other (voluntary) updates relevant for an emergency health response

2 It needs to be underlined that other changes not listed in Section 4.1 Part B of Annex VIII may  
3 take place and these may be relevant for the purposes of the Regulation, in particular for an  
4 emergency health response (e.g. a change in the contact details of the submitter or in the  
5 physical parameters of the mixture). Furthermore, the submitter may want to correct  
6 information for different reasons (e.g. spelling mistakes, which are particularly relevant when  
7 affecting mixture identifiers) or update a notification with new information (e.g. change in  
8 packaging type).

9 The submitter is recommended to voluntarily update the submission as soon as one or more  
10 pieces of the information not listed in Section 4.1 Part B of Annex VIII changes. It is important  
11 that a submission always reflects the most recent information about a product.

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### 14 7.4.4 How updates are technically handled

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16 While all the changes described above require or should trigger an update of the information  
17 submitted (depending on the legal or voluntary reason), they may be handled differently by  
18 the system at the technical level in order to respond to the need of the ultimate user, i.e. the  
19 poison centres.

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21 From the submitter's perspective it will always be an update of the submitted information, but  
22 from a technical point of view, different changes (either listed under Section B.4.1 of Annex  
23 VIII or not) may trigger different "scenarios" which have different consequences for the end  
24 user (i.e. the appointed bodies and poison centres). These are:

25

26 (i) addition of information (e.g. new additional trade name, new additional packaging,  
27 new additional UFI for MiM component); the information originally submitted  
28 remains relevant for the poison centre (e.g. mixture keep being placed on the  
29 market with the original name in addition to the new one).

30 (ii) replacement of old, no longer relevant information with new relevant information  
31 (e.g. new classification due to changes in the criteria; the original classification is  
32 not relevant anymore; new contact information for rapid access to additional  
33 product information); the information originally submitted is not relevant anymore  
34 for the emergency responders even for products already on the market only the new  
35 information should be considered.

36 (iii) creation of a technically new 'submission record' as a change in composition leads  
37 *de facto* to two different products on the market; the two sets of information  
38 (referring to the original and new composition) remain relevant (both products may  
39 remain on the market for a long time).

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### 42 Examples and clarifications

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44 Table 5 below presents some examples of changes and the associated scenarios. In most cases  
45 they apply to both single and group submissions. Information specific for updates of group  
46 submissions, when different from single submissions, can be found in the next section (7.4.5).

47

### 48 Table 5: Examples of possible changes requiring an update and their related 49 scenarios.

| Changes  | Legal requirement or voluntary update | Scenario triggered  |
|--|---------------------------------------|---|
| Addition of a new trade name only <sup>(a)</sup> .   | Legal requirement                     | Scenario (i) – addition of information.   |
| Addition of a new UFI only <sup>(a)</sup> .  | Legal requirement                     | Scenario (i) – addition of information.   |
| Modification of the classification for health or physical hazard <sup>(b)</sup> following change in classification criteria.                     | Legal requirement                     | Scenario (ii) – replacement of old with new information.                                  |
| Addition of new toxicological information (e.g. results from new tests on the mixture become available). The existing information remains valid. | Legal requirement                     | Scenario (i) – addition of information.   |
| New packaging<br><br><i>Note, the mixture in original packaging may remain on the market for long time.</i>                                      | Voluntary                             | Scenario (i) – addition of information.   |
| Supplier changes MiM UFI but the composition remains the same (change due to commercial reasons)   | Legal requirement                     | Scenario (i) – addition of information<br><br><i>Note that a new UFI is not required.</i> |
| Change in telephone number for rapid access to additional product information  | Voluntary                             | Scenario (ii) – replacement of old with new information.                                  |

| Changes  | Legal requirement or voluntary update | Scenario triggered  |
|--|---------------------------------------|---|
| Addition, substitution <sup>(c)</sup> , deletion of component(s).<br>Supplier changes MiM UFI due to compositional changes of MiM, which impact composition of final mixture<br>(for group submissions with perfumes, fragrances or generic product identifiers, see below 7.4.5). | Legal requirement                     | Scenario (iii) – creation of a technically new ‘notification record’.<br><i>Note that a new UFI must be provided.</i> |
| Modification of reported concentration ranges, <b>beyond</b> the indicated range.  | Legal requirement                     | Scenario (iii) – creation of a new ‘notification record’.<br><i>Note that a new UFI must be provided.</i>             |
| Modification of reported exact concentration <b>beyond</b> the indicated range   | Legal requirement                     | Scenario (iii) – creation of a new ‘notification record’.<br><i>Note that a new UFI must be provided.</i>             |

**Notes to the table:**

(a) Rationale: products with the old identifier may still be on the market for an unspecified period of time.

(b) The classification of a mixture may change when a new harmonised classification of a component in the mixture is agreed or when new information becomes available. In that case, an update is required no later than when the new classification becomes applicable.

(c) Substitution is in this case intended with a component which is chemically different. If a component is replaced by another one which is chemically the same (i.e. same composition and hazard profile) but (e.g.) from a different supplier, it is not considered to be substitution.

(d) In case there is a difference in the definitions of industrial, professional or consumer use under national and the harmonised systems, an update for this reason only is not required until the end of the transitional period (1 January 2025).

**7.4.5 Updates – special cases with generic product identifiers**

When ingredients covered by the generic product identifiers “perfumes”, “fragrances” or “colouring agents” are included (see section 5.3), an update is not required if a perfume, fragrance or colouring agent for which a generic product identifier can be used is added, substituted or removed from the mixture. This applies as long as the total concentration of

1 ingredients covered by the generic product identifier remains below the allowed maximum  
2 level (5% for perfumes/fragrances and 25% for colouring agents) and none of those  
3 ingredients is classified for any health hazard.

4 In addition, it should also be mentioned that for “perfume” or “fragrance” components, with a  
5 total concentration below 5% and not classified or only classified for skin sensitisation  
6 Category 1, 1A or 1B or aspiration toxicity, there is no need to provide the concentration  
7 (exact or range) of the single components. This means that variations in the components'  
8 concentration within the limits mentioned above do not require to update the submission.

9 When changes are made to components declared as generic product identifiers in a group  
10 submission, refer to section 7.4.6 below.

**11 7.4.6 Updates – special cases with group submissions**

**12**  
**13 *Addition, substitution, deletion of perfumes and fragrances (covered and not covered***  
**14 *by generic product identifiers) in a group submission***  
**15**

16 When the perfumes or fragrances in a group submission change (if added, substituted or  
17 removed) in one or more of the mixtures in the group, the list of mixtures and the fragrances  
18 or perfumes they contain as required in Annex VIII Section 3.1 must be updated. If the change of  
19 perfumes or fragrances is the only change, a new UFI is not required.

20  
21 Nevertheless, if a perfume/fragrance covered by the generic product identifier is added, but  
22 the total concentration of the generic product identifiers remains <5 %, no update is required.

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24 It is to be reminded that if the change leads to an increase in the content of perfumes or  
25 fragrances in a certain mixture above 5%, this cannot be part of the same group submission  
26 and a new submission is required.

27  
28 Note: The rules for updates are one of the factors to be taken into consideration when it is  
29 possible to decide between standard and group submission. The decision needs to take into  
30 account not only the convenience of preparing the initial submission, but also the  
31 consequences for the updates in the future.

**32**  
**33 Examples and clarifications**  
**34**

35 **Example 25:** Changes in a group submission for two mixtures with a difference in  
36 perfume/fragrance components, submitted to an appointed body  
37

| <b>GROUP SUBMISSION OF TWO MIXTURES WITH DIFFERENCE IN PERFUME/FRAGRANCE COMPONENTS</b>         |  |                           |                             |
|---|--|---------------------------|-----------------------------|
| <u>UFI</u> : C4P7-GHVS<br>ED8M-42DH<br><u>Classification</u> : #<br><u>Product Category</u> : # | <u>Product names</u> :<br>- Trade name 1<br>- Trade name 2 |                           |                             |
| Components  | Percentage   | Actual conc. <sup>a</sup> | Classification <sup>b</sup> |
| Chemical name comp. A   | 60-80%   |                           | not classified              |
| Chemical name comp. B   | 7-10%  |                           | other                       |
| Chemical name comp. C   | 11-14%   |                           | major concern               |

|   |                             |     |                           |
|---|-----------------------------|-----|---------------------------|
| Chemical name comp. D                     | 1-2%                        |     | major concern             |
| Fragrances (Generic Product Identifier)   | < 5% <5%                    | 2   | not classified            |
| Chemical name fragrance 1                 | 1-4%                        | 1.5 | other                     |
| Chemical name fragrance 2                 | 0.3-0.6%                    | 0.4 | major concern             |
| Chemical name fragrance 3                 | 1-2%                        | 1.1 | major concern             |
| Chemical name fragrance 4                 | not applicable<br>(but <5%) | 0.5 | other (skin sens. cat. 1) |
| 'Perfume MiM'<br>UFI: A67T-VHG2-DMM4-NH2A | 1-4%                        | 1.8 | other                     |

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The total concentration of perfumes/fragrances in each mixture cannot exceed 5% in order to qualify for a group submission [A.4.3].

The total concentration of fragrances identified with a given generic product identifier in each mixture cannot exceed 5% [B.3.2.3].

Fragrances not classified or only classified for skin sensitisation Category 1, 1A or 1B or aspiration toxicity do not need information on concentration if the total concentration of such fragrances) in each mixture does not exceed 5% [B.3.4.2].

#### LIST OF PERFUMES/FRAGRANCES IN THE MIXTURES TRADE NAME 1 AND TRADE NAME 2

| Name         | Fragrance or perfume                    | Classification <sup>b</sup> |
|--------------|---|-----------------------------|
| Trade name 1 | Fragrance chemical name 1               | other                       |
|              | Fragrance chemical name 3               | major concern               |
|              | 'Perfume MiM'<br>A67T-VHG2-DMM4-NH2A    | other                       |
| Trade name 2 | Fragrance chemical name 2               | major concern               |
|              | Fragrance chemical name 4               | other (skin sens. cat. 1)   |
|              | Fragrances (Generic Product Identifier) | Not classified              |

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#### Notes to the tables:

(a) Actual concentrations are reported for internal calculation purposes only; they are not necessarily required to be indicated in the submission.

(b) Classifications are indicated in this example with three categories: 'major concern' (list of classifications in B3.4.1], 'other' (all other hazard classifications) and 'not classified'.

The following changes may occur affecting the information included in the submission

exemplified above:

- *Change of concentration of generic product identifiers*

If the concentration of *fragrances* is changed, but still remains <5 %, no update is required.

- *Change of concentration of classified perfume/fragrance component*

If the concentration of *Chemical name fragrance 2* is changed to <0,3 % or >0,6 % an update with a new concentration interval for *Chemical name fragrance 2* is required, but an updated list is not.

- *Addition of classified perfume/fragrance to a mixture in a group submission*

- If *Chemical name fragrance 1* is added to Trade name 2, but the concentration is still within the interval 1-4 %, only an updated list is required.
- If a classified perfume/fragrance, not declared among the components, is added to either of the mixtures, Trade name 1 or Trade name 2, an update of the components is required, as well as an updated list.

- *Addition of not classified perfume/fragrance to a mixture in a group submission*

- If a perfume/fragrance not classified for any health hazards is added, but the total concentration of the generic product identifiers remains <5 %, no update is required.
- If a perfume/fragrance not classified for any health hazards is added and it is indicated with the chemical name, an update of the component is needed. If the total concentration of this perfume/fragrance together with the generic product identifiers remains <5 %, the concentration does not need to be indicated [B.3.4.2].

- *Deletion of a classified perfume/fragrance in a mixture in a group submission*

- If *Chemical name fragrance 3* is removed from Trade name 1 an update of the components is required as well as an updated list.

Note: the total concentration of all perfumes and fragrances contained in each mixture of the group should not exceed 5%. Otherwise the mixtures cannot be grouped and separate standard submissions are required.

## 7.5 Validity of the submission

In practice, many products may remain on the market (on shelves, in storehouses or in households) for years after a company has ceased marketing those products. Information may still be needed by poison centres in case of accidental exposure to those products. Therefore, submissions related to those products cannot just be retracted or deleted upon the cease of marketing or after the last placing on the market.

It is not possible to establish for every product – based on the type, use and market – a specific deadline after which the possibility of exposure to a mixture by consumers, professionals and even industrial users can reasonably be excluded. For this reason, deletion or removal of the submitted information from the databases has not been foreseen and, in principle, the information remains available to appointed bodies and poison centres (and in general for the personnel dealing with emergency response) indefinitely.

It is the responsibility of the importer/downstream user to make sure that the submission is correct at any time and keep it up to date until the last date of placing on the market. The



1 companies will have the possibility to indicate via the PCN portal to authorities the ceasing of  
2 their activity. In case new relevant information becomes available to the company after the  
3 last placing on the market, it is recommended that the information submitted for the purposes  
4 of Annex VIII is voluntarily updated in order to facilitate the emergency response work. It  
5 should be noted that after the last placing on the market, appointed bodies and/or poison  
6 centres can still request additional information from submitters, if needed for emergency  
7 reasons or statistical analysis for improved risk management measures in the context of 3.2.  
8 of Part A of Annex VIII. It is at the discretion of each Member State to decide whether to apply  
9 a cut-off date to 'clean' information from their databases for practical reasons, for example 20-  
10 25 years after the submitter indicated cease of the activity (diminishing the likelihood of an  
11 incident), or after, for example, 10 years if there has been no incident involving the mixture  
12 during that period.

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## 1 **8. Additional support**

2 Below is a list of additional sources of information and support tools, which may be relevant  
3 and is currently available:

### 4 **ECHA Poison Centres Website** (<https://poisoncentres.echa.europa.eu/>)

- 5 - For 'News' updates on the ECHA poison centre project
- 6 - Frequently asked Q&As which are regularly updated on a range of topics
- 7 - UFI generator and the user guide in all EU languages
- 8 - Tools for the preparation and submission of information
- 9 - European product categorisation system and manual
- 10 - Targeted support pages e.g. for industry

11 **ECHA Website, support section** (<https://echa.europa.eu/support>), which contains a range  
12 of support material besides the Guidance, including:

- 13 - Webinars
- 14 - Animations
- 15 - Publications e.g. 'In brief' material
- 16 - Helpdesk support

### 17 **National Helpdesks**

18 National Helpdesks have been established as the first point of contact for questions on  
19 regulatory advice in your own language. You can find more details on your National Helpdesk  
20 here: <https://echa.europa.eu/support/helpdesks>

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